SUPREME COURT, U.S.

IN THE

Supreme Court of the United States

OCTOBER TERM, 1974

No. 74-501

WYETH LABORATORIES, a division of American Home Products Corporation, a Delaware corporation,
Petitioner,

v.

EPIFANIO REYES, individually and as next friend of Anita Reyes, a minor,
Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

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PRESS OF BYRON S. ADAMS PRINTING, INC., WASHINGTON, D. C.

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Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

The petitioner, WYETH LABORATORIES, prays that a writ of certiorari issue to review the opinion and judgment of the United States Court of Appeals for the Fifth Circuit rendered in these proceedings on July 31, 1974.

OPINION BELOW

The opinion of the Court of Appeals is reported as *Reyes* v. *Wyeth Laboratories,* 498 F.2d 1264 (5th Cir. 1974), and appears at Appendix A, *infra,* at pp. 2a, *et*

seq. The case was tried to a jury in the United States District Court for the Southern District of Texas, Brownsville Division, and that court did not render an opinion.

JURISDICTION

The judgment of the Court of Appeals was entered on July 31, 1974, Appendix A, *infra,* at p. 1a. This petition for certiorari was filed less than 90 days from the date aforesaid. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

QUESTIONS PRESENTED

1. Whether, by enactment of the Federal Food, Drug, and Cosmetic Act of 1938, 52 Stat. 1040 (1938), as amended, 21 U.S.C. §§ 301, *et seq.* (1970), and the Public Health Service Act, 58 Stat. 702 (1944), as amended, 42 U.S.C. §§ 262, *et seq.* (1970), Congress has so pre-empted the field of law applicable to the labeling of prescription biological drug products that it was error for the courts below to dispose of this case solely on the basis of local tort law.

2. Whether the Court of Appeals contravened the public health policy of the State of Texas and of the United States and erred in its application of Texas law by holding, in the face of statutorily expressed public policy of Texas to the contrary and in disregard of the holding in the only Texas case in point, that under Texas law a manufacturer of a prescription drug, used to immunize large segments of the population against paralytic polio, is required to warn the ultimate consumer of the dangers of vaccination, even though admittedly adequate warnings have been given to the physician-administrators of the state public health facility dispensing the drug.

CONSTITUTIONAL, STATUTORY, AND FEDERAL REGULATIONS INVOLVED

The Public Health Service Act provides:

Sec. 351.

* * *

(b) No person shall falsely label or mark any package or container of any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid; nor alter any label or mark on any package or container of any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid so as to falsify such label or mark.

* * *

(g) Nothing contained in this chapter shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of the Federal Food, Drug, and Cosmetic Act." [42 U.S.C. § 262(b), (g) (1970).]

The Federal Food, Drug, and Cosmetic Act provides at Sections 502 and 503:

"Sec. 502. Misbranded drugs and devices.

A drug or device shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

* * *

(f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner

and form, as are necessary for the protection of users: *Provided,* That where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement." [21 U.S.C. § 352(a),(f) (1970).]

* * *

"Sec. 503. Exemptions in case of drugs and devices.

* * *

(b)(2) Any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be exempt from the requirements of section 502, except paragraphs (a), (i) (2) and (3), (k), and (l), and the packaging requirements of paragraphs (g), (h), and (p), if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber, and, if stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in such prescription. This exemption shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail, or to a drug dispensed in violation of paragraph (1) of this subsection." [21 U.S.C. § 353(b) (1970).]

The provisions of 21 C.F.R. § 1.106 are in pertinent part as follows:

"§ 1.106 Drugs and devices; directions for use.

(a) *Adequate directions for use.* "Adequate directions for use" means directions under which the layman can use a drug or device safely and for the purposes for which it is intended. Di-

rections for use may be inadequate because (among other reasons) of omission, in whole or in part, or incorrect specification of:

(1) Statements of all conditions, purposes, or uses for which such drug or device is intended, including conditions, purposes, or uses for which it is prescribed, recommended, or suggested in its oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drug or device is commonly used; except that such statements shall not refer to conditions, uses, or purposes for which the drug or device can be safely used only under the supervision of a practitioner licensed by law and for which it is advertised solely to such practitioner.

(b) *Exemption for prescription drugs.* A drug subject to the requirements of section 503(b)(1) of the act shall be exempt from section 502(f)(1) if all the following conditions are met:

* * *

(4) Any labeling, as defined in section 201(m) of the act, whether or not it is on or within a package from which the drug is to be dispensed, . . . contains: (i) Adequate information . . . under which practitioners licensed by law to administer the drug can use the drug safely and for the purposes for which it is intended . . . ."

The language of 21 C.F.R. § 1.2 is as follows:

"§ 1.2 Labeling; label; definitions.

(a) Labeling includes all written, printed, or graphic matter accompanying an article at any time while such article is in interstate commerce or held for sale after shipment or delivery in interstate commerce.

(b) 'Label' means any display of written, printed, or graphic matter on the immediate con-

tainer of any article, or any such matter affixed to any consumer commodity or affixed to or appearing upon a package containing any consumer commodity."

The relevant statute of the State is Vernon's Education Code of Texas, Section 2.09, which provides in part as follows:

"No person may be admitted to any elementary or secondary school or institution of higher education unless he has been immunized against . . . poliomyelitis . . . . except as provided in Subsection (c)."

The complete text of § 2.09 is reproduced in full at Appendix B, *infra*, at pp. 60a-61a.

STATEMENT OF THE CASE

On May 8, 1970, Anita Reyes, an 8-month-old infant, received a dose of trivalent oral polio vaccine at a State of Texas County Health Department Clinic in Hidalgo County, Mission, Texas. The vaccine was administered in the course of an epidemic as declared by the United States Government through the Center for Disease Control as a part of an epidemic control program conducted pursuant to the recommended policy of the Center for Disease Control in Atlanta, Georgia. Of the 33 cases of polio reported throughout the Nation during the year 1970, 22 occurred in Texas. All but one of these cases occurred in the Rio Grande Valley, where Anita Reyes resides, an area of concentrated Mexican-American population; and 1 out of every 3 of the Texas cases were in Hidalgo County. Center for Disease Control, *Annual Poliomyelitis Summary—1907*, at 1-4 (Sept. 30, 1971).

The vaccine Anita received was part of 400 vials manufactured and shipped by Petitioner in interstate commerce in accordance with Federal law and regulations. It was shipped by the Texas Department of Health in Austin, Texas, to the Hidalgo County Health Department, and had been purchased by the Texas Health Department under a competitive bid from Petitioner, Wyeth Laboratories. Wyeth Laboratories is a division of American Home Products Corporation and is the distribution outlet for Wyeth Laboratories, Inc., a wholly owned subsidiary of American Home Products.

Each vial of this vaccine contained a "package circular" detailing the dangers associated with taking the vaccine. The registered public health nurse at the Mission Health Clinic of the Hidalgo County Health Department had read the package insert. No warning of the inherent danger, characterized by the Court of Appeals as "statistically miniscule" (498 F.2d at 1274), was given by the public health nurse to Anita's mother. Approximately twenty days after she received the vaccine, it was determined that Anita had contracted Type I paralytic polio.

Respondent, Epifanio Reyes, filed suit individually, and as next friend of his minor daughter, Anita Reyes, against Petitioner in the Federal District Court for the Southern District of Texas, Brownsville Division, with jurisdiction based on diversity of citizenship. The jury concluded that Petitioner's vaccine was the cause of Anita's polio and rendered a verdict against Petitioner. On appeal, the United States Court of Appeals for the Fifth Circuit held Petitioner liable under Texas products liability law for failing to warn Anita's parents of the danger inherent in the vaccine.

REASONS FOR GRANTING THE WRIT

A. Congress Has So Pre-empted the Field of Law Applicable to Labeling of Prescription Biological Drug Products That It Was Error for the Courts Below to Dispose of the Case Solely on the Basis of Local Tort Law.

This case involves an important question of Federal supremacy which has never before been specifically considered by this Court. The manner in which this question is resolved will have a profound impact on public health care throughout our Nation, particularly on national programs of disease prevention.

Section 502(a) of the Federal Food, Drug, and Cosmetic Act provides that a drug shall be deemed to be misbranded if its labeling is false or misleading in any particular. 21 U.S.C. § 352(a). A drug will also be deemed misbranded according to Section 502(f) if its labeling does not bear "(1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health . . . ." 21 U.S.C. § 352(f).

By Federal regulation, 21 C.F.R. § 1.106(a), the term "adequate directions for use" as used in Section 502(f) of the Act means "directions under which the layman can use a drug or device safely and for the purposes for which it is intended." These requirements, however, are not applicable to prescription drugs because of the provisions of Section 503 of the Act. That section exempts from the "directions for use" requirements of Section 502(f) any drug which is dispensed on the order of a practitioner licensed by law to administer such drug. This exemption of prescription drugs is further reflected in 21 C.F.R. § 1.106 (a)(1), which states that the "directions for use" re-

quirements shall not apply "to conditions, uses, or purposes for which the drug or device can be safely used only under the supervision of a practitioner licensed by law and for which it is advertised solely to such practitioner." The provisions of Section 502(a) prohibiting false or misleading labeling remain applicable to prescription drugs.

The foregoing provisions are not the only Federal laws regulating the labeling of biological drug products. The Public Health Service Act, 58 Stat. 702 (1944), as amended, 42 U.S.C. §§ 262, *et seq.*, contains detailed requirements on the licensing, labeling, and marketing of any virus, serum, toxin, antitoxin, vaccine, or similar biological product in interstate commerce. Section 351 (g) provides explicitly, however, that: "Nothing contained in this Act shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of the Federal Food, Drug, and Cosmetic Act." 42 U.S.C. § 262(g).

It has not been and cannot be alleged that the labeling which Petitioner provided with its trivalent polio vaccine in this case was in any way false or misleading. It was the standard labeling developed with approval of Federal officials through long experience, and it was properly shipped in interstate commerce to the public health officials in charge of the immunization program out of which this case arose. That labeling, as required by Federal law, was directed to health professionals and contained all necessary directions and warnings. Because of the scientific and medical complexities surrounding this vaccine, as with any prescription drug product, adequate labeling could have been directed only to health professionals and not to the ultimate lay consumer.

The courts below would have the manufacturer attempt to provide some form of written information to the lay consumer regarding the use of this vaccine. Without question any such statement would amount to "labeling" under Federal law and regulations. That term is defined at Section 201(m) of the Act as meaning "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article."

The term is further explained by Federal regulation at 21 C.F.R. § 1.2:

> "§ 1.2 Labeling; label; definitions.
>
> (a) Labeling includes all written, printed, or graphic matter accompanying an article at any time while such article is in interstate commerce or held for sale after shipment or delivery in interstate commerce.
>
> (b) 'Label' means any display of written, printed, or graphic matter on the immediate container of any article, or any such matter affixed to any consumer commodity or affixed to or appearing upon a package containing any consumer commodity."

The court below has committed a fundamental error which, if not corrected, will have a profoundly adverse impact upon public health immunization programs in the future. In its attempt to equate the situation in this case with the sale of over-the-counter drugs, and draw therefrom a duty on the part of the manufacturer to provide labeling providing laymen with "adequate directions for use" of trivalent oral polio vaccine, the Court of Appeals' decision threatens to wreak havoc with our Nation's health care delivery system.

Erroneously, and contrary to Federal law, the Court of Appeals has assumed that the manufacturer, or anyone other than trained and licensed health professionals dealing directly with their patients, can provide "adequate directions for use" for prescription drug products which are meaningful to laymen, many of whom may be of limited educational background. This case does not involve the purchase of a common analgesic or an antacid at a local drug store. It involves the administration by public health authorities in an epidemic situation of a potent and complex vaccine properly manufactured and shipped in interstate commerce pursuant to Federal law.

The decision to conduct mass immunization in this case was made by public health authorities. The professional labeling accompanying the vaccine in question was made available by Petitioner to those authorities. The inherent risk involved in administering the vaccine was known to them. No representative of Petitioner was present during administration of the vaccine, and it would stretch the bounds of credibility to suggest that it should be otherwise.

The entire context of the Federal Food, Drug, and Cosmetic Act, as it concerns the labeling of prescription drug products, shows without question that Congress intended to pre-empt this area of interstate commerce. While the extension of Federal control into traditionally local matters is always a delicate exercise of legislative authority and requires accommodation between the needs of central control and the maintenance of local institutions, where the intent of Congress is clearly to pre-empt the field in matters regarding interstate commerce that intention must prevail. *Davies Warehouse Co.* v. *Bowles,* 321 U.S.

144 (1944). No one will question that where State and Federal laws do not overlap, a State's jurisdiction is unimpaired. *Id.; Algoma Plywood & Veneer Co.* v. *Wisconsin Employment Relations Board,* 336 U.S. 301 (1949). But as this Court has also noted in a related context involving the predecessor of the Federal Food, Drug, and Cosmetic Act:

> "... [I]t is equally well settled that the State may not, under the guise of exercising its police power or otherwise, impose burdens upon or discriminate against interstate commerce, nor may it enact legislation in conflict with the statutes of Congress passed for the regulation of the subject, and if it does, to the extent that the state law interferes with or frustrates the operation of the acts of Congress, its provisions must yield to the superior Federal power given to Congress by the Constitution. *Texas & Pacific Ry. Co.* v. *Abilene Cotton Oil Co.,* 204 U.S. 426; *Northern Pacific Ry. Co.* v. *Washington,* 222 U.S. 370; *Southern Ry. Co.* v. *Reid,* 222 U.S. 424; *Second Employers' Liability Cases,* 223 U.S. 1; *Savage* v. *Jones, supra,* 533." *McDermott* v. *Wisconsin,* 228 U.S. 115, 131-132 (1913).

Therefore, where Congress has taken jurisdiction of a particular matter or type of controversy affecting interstate commerce, the States, through their courts, may be precluded from adjudging the controversy and extending their own forms of relief. *Garner* v. *Teamsters Union,* 346 U.S. 485 (1953).

In the situation now at hand the purpose of Congress is clear and manifest. The labeling of prescription drug products shipped in interstate commerce is subject entirely to Federal law and regulation, and the States are without power to impose contrary restraints in this area. When the manufacturer of a prescription drug

product has complied fully with the provisions of Federal law regarding the labeling of that product, he has completed his obligation to the public. Indeed, he should have no other obligation to the public with regard to prescription drug labeling than to comply with Federal law, whether that obligation be asserted in the form of criminal sanctions or civil or tort liability. Moreover, throughout the Federal statutes and regulations on this subject there is an inherent recognition of the sanctity to be accorded the doctor-patient relationship. No drug manufacturer is required or even allowed under Federal law to interpose himself between doctor and patient.

The decision of the Court of Appeals below, if left standing, would not only violate Federal policy as promulgated by Congress and the Secretary of Health, Education, and Welfare but would also inevitably breed a new form of liability suit brought by individuals against drug manufacturers based on unavoidable injuries due to inherent risks in taking prescription medication on the advice of health professionals. Such a result would alter in a fundamental way the health care delivery system in this Nation. Manufacturers, not health professionals, would be ultimately responsible for the administration of prescription drugs to individual patients.

The effect of the Court of Appeals' decision would be to remove the public health physician in particular from the relationship between the patients of a public health clinic and the manufacturers whose drugs are used to further the goals of such an institution. To the class of persons dependent upon the services provided by a public health clinic, the lower court's decision would have a devastating impact. These per-

sons would be faced with a choice which they are unprepared to make and which would be made for them if they had the financial resources to seek health care from a private physician. This is true because, as Petitioner has repeatedly emphasized, in the administration of polio vaccine there is no basis for the individualized medical judgment on which the court below rests its decision. This fact was either ignored or never understood by the Court of Appeals. For the Nation as a whole, but particularly for large agricultural states such as Texas with a significant number of poorly educated migrant laborers among whom the incidence of communicable diseases such as polio is tragically high, the lower court's conclusion that public health authorities cannot play a meaningful role in administering prescription drugs used in immunization programs will have serious repercussions because of the increased likelihood of communicable disease epidemics. This is especially true should manufacturers of polio vaccine be forced to discontinue its sale to public health institutions because of the problem of insuring that adequate warnings are given. The Court of Appeals' reference to cost-benefit analysis cuts both ways. Also, the lower court's suggestion that the manufacturer's loss "be passed on to the public in the form of price increases to [its] customers," 498 F.2d at 1294, is an unrealistic assessment. Public health institutions are by far the largest-volume purchasers of Petitioner's vaccine, and they are financed by State and Federal governments which have neither the intention nor the authority to become the manufacturer's insurers.

The assumption of necessary and unavoidable risk in the case of administration of any potent prescription

drug is a medical judgment to be made by the health professional in dealing with his patient. To place that risk at the door of drug manufacturers will, among other things, have a chilling effect on their ability to cooperate with public health officials in epidemic situations such as that in this case. It is Federal policy to leave the decision on administration of drugs similar to the vaccine here to individual health professionals in the context of their own relationships with their patients—even in public health situations. That policy is clearly seen in the Federal statutes and regulations. It is a policy which the decisions below would destroy.

B. The Decision of the Court of Appeals Is in Conflict with Applicable Texas Law and Federal and State Public Policy on the Important Question of Whether the Manufacturer of a Prescription Drug Has a Duty to Warn the Ultimate Consumer of Possible Risks Involved in Taking the Drug.

This case merits review because of the significant public health ramifications which will flow from the lower court's holding that the manufacturer of a prescription drug, administered in the course of a Federally approved State program designed to immunize segments of the population against a highly communicable disease, is required to warn the ultimate consumer of the danger inherent in the drug, even though an adequate warning has already been given to the physicians in charge of the public health facility which dispenses the drug. The importance of this issue cannot be overstressed, since it is certain that the impact on future operations and decisions of public health authorities—both State and Federal— will be disruptive not only with respect to the administration of polio vaccine, but also with respect to other drugs administered in public health clinics or in the course of publicly sponsored mass immunization programs.

The Court of Appeals failed to follow applicable Texas law, and ignored the very strong public policy of the State of Texas in preventing the spread of communicable disease. Review by this Court is needed to correct this misapplication of State law, and to avoid the serious adverse effects which it is certain to produce.

There can be no doubt that Texas has a strong interest in preventing the spread of communicable diseases. In order to implement this policy, Texas law requires that students be immunized against certain communicable diseases, including poliomyelitis. Vernon's Education Code of Texas § 2.09 (1971). [See Appendix B, *infra*, pp. 60a-61a.]

The success of such programs of immunization in virtually eliminating epidemics of poliomyelitis is well known. As the Court of Appeals recognized, much of the credit for the elimination of polio from the United States is due to the combined efforts of Federal and State public health authorities and the manufacturers of polio vaccine. 498 F.2d at 1270. Substantial participation in such immunization programs by the Federal Government indicates the national importance of these efforts.[1] The current policy of the Federal Gov-

[1] For the past 10 years, the United States Public Health Service, an agency of the Department of Health, Education, and Welfare, has advocated the use of oral polio vaccines to combat the threat of poliomyelitis and has played a substantial role in encouraging mass immunization programs. *See* Report of the Surgeon General's Special Advisory Committee on Oral Poliomyelitis Vaccines, 190 A.M.A. Journal at 49-51 (October 1964). This policy has been frequently reiterated. *See, e.g.*, 16 A.M.A. Journal (August 1967); 18 A.M.A. Journal (October 1969); 21 A.M.A. Journal (June 1972). In line with this Federal policy the United States Public Health Service through the Center for Disease Control in Atlanta, Georgia, has been an active participant in watching for

ernment is manifested by a recent proclamation in which the President of the United States urged "all parents, educators, and medical personnel to exert renewed efforts during this week and throughout the year to immunize every American child against diseases for which vaccines are available." Presidential Proclamation 4329, *Immunization Action Week 1974,* October 21, 1974 [39 Fed. Reg. 37629 (Oct. 23, 1974); See Appendix C, *infra,* p. 62a.]

In an epidemic situation the public health physician has only one choice to halt the spread of communicable disease. That choice is mass immunization. Under the Court of Appeals' decision below the manufacturer of the prescription drug to be used in the immunization program would be required to interfere with that choice by carrying a warning to the ultimate consumer. The effect of that holding would be to undermine the ability of public health physicians to act decisively and effectively to control threatened epidemics, such as the situation which existed in Hidalgo County in 1970.

The polio vaccine administered here was not defectively manufactured. It was "exactly what its makers and the Texas public health authorities intended it to be." 498 F.2d at 1273. Even so, there remained the chance—established statistically at ranges from 1 in 1 million to 1 in 16 million— that one ingesting the vac-

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and in helping state and local authorities control outbreaks of poliomyelitis. (For examples of this participation refer to the official publication of the Center for Disease Control, Morbidity and Mortality Weekly Report, for the following weeks: July 28, 1963 (Pennsylvania); August 2, 1963 (Walker County, Alabama); April 3, 1965 (Pinal County, Arizona); May 22, 1965 (Scotts Bluff, Nebraska); June 26, 1965 (Arizona); July 2, 1966 (Texas); August 13, 1966 (Texas); February 24, 1968 (Hidalgo County, Texas); May 30, 1970, (Hidalgo County, Texas); and September 19, 1970 (San Antonio, Texas).)

cine would contract polio.[2] Unlike most other prescription drugs, however, it cannot be determined by a physician on the basis of an individual's medical history, physical condition, or from a medical examination whether a particular person is susceptible to contracting polio from ingestion of this vaccine. This is especially true of infants and young children. Thus, the medical judgment involved can be made just as intelligently on a generic basis by public health physicians as it can on an individual basis by a private physician, the patient, or the patient's parents. A warning of some sort by the manufacturer to the ultimate consumer would not provide for a more informed choice, but would merely impede the efforts of public health authorities to prevent the outbreak of an epidemic.

Petitioner's liability is grounded on its failure to warn Anita's mother of the statistical probabilities involved in her daughter's taking the vaccine. In the Fifth Circuit's view, the necessity for such a warning stems from the unavoidably unsafe nature of the vaccine and the need when dealing with such a drug for "an individualized medical judgment that this treatment or medication is necessary and desirable for this patient." 498 F.2d at 1295. To hold Petitioner strictly liable in tort, the court necessarily concluded that an individualized medical judgment was necessary and that this func-

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[2] Generally, these statistics were compiled by epidemiologists. Epidemiology is a specialized field of medicine dealing with public health, which is based on the observation of disease and thereafter, by statistical methods, trying to arrive at a conclusion as to the possible source of the disease. 498 F.2d at 1271 n. 3. The statement in the text does not mean that one of every million persons who takes the vaccine will contract polio; it means that within the ranges given, it is statistically compatible with the possibility that the vaccine caused the illness.

tion was not performed by the State's public health physicians. This two-pronged conclusion is the foundation for the court's decision because of the rule "that where *prescription* drugs are concerned, the manufacturer's duty to warn is limited to an obligation to advise the prescribing physician of any potential dangers that may result from the drug's use." *Id.* at 1276.

Although Petitioner's vaccine was conceded to be a prescription drug, the court avoided the prescription drug rule by reasoning, in essence, that it would not apply unless there was a face-to-face meeting of patient and physician. Absent such a meeting the principles applicable to the sale of over-the-counter drugs, which require a warning to the ultimate consumer, govern the manufacturer's discharge of its duty. *Id.* at 1276. Considered against the backdrop of public health policy, the Fifth Circuit's all-or-nothing approach not only threatens the effectiveness of the State's program to prevent the spread of communicable disease but also represents an egregious misapplication of Texas products liability law.

The Circuit Court's misapplication of Texas law is highlighted by its improper treatment of the only Texas case in point on the issue whether Petitioner's warning to the public health authorities was sufficient to discharge its duty. In *Gravis* v. *Parke-Davis & Co.*, 502 S.W.2d 863 (Tex.Civ.App.—Corpus Christi, 1973), the court was concerned with a prescription drug manufacturer's duty to warn the ultimate consumer of the dangers of a particular drug.

> "We hold that it is unreasonable to demand that the manufacturer of drugs specifically warn each and every patient that receives drugs prescribed by the physician *or other authorized persons.* The

> entire system of drug distribution in America is set up so as to place the responsibility for distribution and use upon professional people. The laws and regulations prevent prescription type drugs from being purchased by individuals without the advice, guidance and consent of licensed physicians and pharmacists. These professionals are in the best position to evaluate the warnings put out by the drug industry." 502 S.W.2d at 870. (Emphasis added.)

Obviously, the approach taken by the court below is directly contrary to the holding in *Gravis*. The *Gravis* court rejected the approach taken by the Fifth Circuit by explicitly recognizing that the central question is whether a "physician or other authorized [person]" has made the decision that a particular drug should be used. A Texas court faced with the circumstances of this case would have held as a matter of law, based on *Gravis*, that the warning to the public health physicians discharged Petitioner's duty to warn anyone else.

A different panel of the Fifth Circuit, applying Texas law, recently held that a Texas physician is not required to inform his patient of all the risks involved in the treatment offered. He must only act as would a reasonable medical practitioner in the same circumstances. *Karp* v. *Cooley*, 493 F.2d 408 (5th Cir. 1974. *See also*, *Wilson* v. *Scott*, 412 S.W.2d 299, 301 (Tex. 1967); *Gravis* v. *Parke-Davis & Co.*, *supra*, 502 S.W.2d at 870.

The underlying rationale of *Karp* is contrary to the approach taken by the Fifth Circuit in this case. Petitioner provided a complete and adequate warning to the appropriate public health officials. These officials,

having determined that a polio epidemic was in progress in the Rio Grande Valley, and acting in accordance with Federal and State policy, determined that every effort should be made to immunize all persons. There can be no doubt that their action complied with the standard outlined in *Karp* as measured by the local and nationwide practices of public health physicians.

The lower court's attempt to distinguish the vaccine involved in this case from other prescription drugs which require no warning to the ultimate consumer is based on the absence of a "prescribing physician, who acts as a 'learned intermediary' between manufacturer and consumer." 498 F.2d 1276. The assessment of risk by public health physicians, and their decision not to warn each recipient is in accord with the standards set in *Karp,* and represents the same type of judgment that a prescribing physician would make. Furthermore, the court below conceded that an individual prescribing physician would be unable to do any more than the State authorities have done in treating a particular patient, since, as the court noted, ". . . the risk appears to be distributed evenly among that substantial segment of the population that is not naturally immune to polio. This is so because the behavior of polio virus in those who contract the disease seems to suggest more a reversion to virulence by the virus than a sensitivity in the vaccine." *Id.* at 1279. Accordingly, an individualized examination of each patient would in no way lessen the risk involved.

Thus, Petitioner, by providing an adequate warning to Texas public health authorities, fully discharged any duty it had under Texas law, as well as Federal law, since the State's authorities could and did func-

tion as a "learned intermediary" whose judgment relieved the manufacturer of a duty to warn the ultimate consumer directly.

In reaching its decision, the Court of Appeals relied almost exclusively throughout its opinion on the reasoning of *Davis* v. *Wyeth*, 399 F.2d 121 (9th Cir. 1968), which also involved a plaintiff who allegedly contracted polio from Petitioner's vaccine. On the facts of this case, the court's reliance on *Davis*, which involved an application of Montana Law, cannot be reconciled with the applicable Texas authorities, or with the strong public policy of Texas in favor of immunizing all the children of the State against polio.

In *Davis* the vaccine was given in 1963 to a 39-year-old man in a nonepidemic environment in the course of a mass immunization program conducted by the local medical society with Petitioner's cooperation. Because of unusual circumstances the vaccine was administered by a pharmacist, rather than by a registered public health nurse or physician. The *Davis* court characterized the vaccine as "new and experimental," as indeed it may have been in 1963, and also observed:

> "A fact sheet put out by [Wyeth] and contained in the book it supplied to clinics was published prior to the Surgeon General's Report and represented the vaccine as completely safe for all ages. A collection of news clippings from Idaho newspapers introduced in evidence by [Davis] shows not only a complete lack of warning but assurances that the vaccine was safe for all." 399 F.2d at 125.

The *Davis* court based its decision, then, on the theory that no adequate warning was given to anyone. This is crucial because there was some evidence that an

adult of that plaintiff's age stood a statistically higher risk of contracting polio than would a child. On these facts, the Ninth Circuit reversed a jury verdict for the defendant, holding that the District Court erred in failing to instruct the jury on the warning issue.

Petitioner does not contend that it has no duty to warn. Rather, it asserts now, as it has continuously (see 498 F.2d at 1275), that its duty was fulfilled. The warning present with each vial of vaccine contains cautionary language regarding administration of the vaccine and no contention has been made that this warning is inadequate. Moreover, the warning in this case was given to physicians in charge of a State's public health program—physicians eminently familiar with the needs of those the program would serve, and to the public health nurse who administered the vaccine. Finally, the vaccine here was given to an 8-month-old child, in an epidemic environment, with the undisputed fact being that children of tender years are most susceptible to polio. These are not distinctions without differences, for they thoroughly undermine the lower court's mechanistic reliance on *Davis*. Petitioner submits that a Texas court would not have regarded *Davis* as controlling on the basis of these factual differences and in view of the State's strong public policy in favor of universal immunization for its children.

That the Court of Appeals erred, to a degree warranting review by this Court, in relying so heavily on *Davis* and in failing to accord any weight to the applicable decisions interpreting Texas law is apparent when the factual context in which the vaccine was administered here is considered.

The court either failed to consider or attached too little significance to the type of health institution at

which Anita Reyes received the polio vaccine. The Mission Health Clinic in Mission, Texas, is run by the Hidalgo County Health Department, which in turn is an arm of the Texas State Department of Health. It is one of many such institutions operating throughout the State of Texas and across the Nation. The clinic is staffed by two registered public health nurses, there being no physician there on a fulltime basis. The crucial decisions are made by medical doctors at the local, county and State level. One of the primary functions of these local public health clinics is to provide health care for those who cannot afford a private physician. Large segments of the population receive communicable disease vaccines, including polio vaccine, free of charge to the recipient at these clinics. As a practical matter, these innoculations against the more common communicable diseases may well be the only health care received by a significant portion of the population.

The need for such services in Texas is obvious. As we have previously mentioned, of the 33 cases of polio reported nationwide in 1970, 22 occurred in Texas, with all but 1 of the cases occurring in an area of concentrated Mexican-American population and the vast majority in the Rio Grande Valley area where Anita Reyes resides. In fact, 7 of the 22 Texas cases were from Hidalgo County. Center for Disease Control, *Annual Poliomyelitis Summary—1970*, at 1-4 (Sept. 30, 1971). We need say no more to illustrate that the problem is not hypothetical or a matter of conjecture—it is an ever-present concern of public health authorities.[3]

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[3] On September 30, 1974, while counsel for Wyeth was preparing this petition, an Associated Press article appeared on the front page of the *Idaho Statesman* in which the Center for Disease Con-

In summary, Petitioner submits that had the issue been submitted to the Texas courts, the State's public policy in favor of polio immunization combined with the admittedly adequate warning to the appropriate State public health authorities would have produced a holding that the manufacturer of this prescription drug was not required, to provide the ultimate consumer with some form of "labeling" about the drug which would include information on the statistical danger of contracting polio by ingesting the vaccine. "[I]t is unreasonable to demand that the manufacturer of drugs specifically warn each and every patient that receives drugs prescribed by the physician or other authorized persons." *Gravis* v. *Parke-Davis & Co., supra,* 502 S.W.2d at 870; *see Karp* v. *Cooley, supra,* 493 F.2d at 420. Texas, by enacting its statute mandating immunization of children against poliomyelitis, has made a policy judgment which the Court of Appeals ignored. A Texas court would have recognized this policy, would have examined the circumstances in which the vaccine was administered, and then would have held as a matter of law that the warning to the public health physicians discharged Petitioner's duty.

It is apparent that the Court of Appeals failed in its duty to construe, interpret, and apply Texas law as would a Texas court. This error can only be corrected if this Court grants Petitioner's writ of certiorari.

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trol in Atlanta, Georgia, a division of the Department of Health, Education, and Welfare, warned that nationwide epidemics of childhood diseases could still erupt. Figures released by the CDC indicated that immunization levels for polio for 1-4 year-old children dropped in 1973 to a low of 60.4 percent, compared to 84.0 percent in 1963. *See also, New York Times,* Oct. 10, 1974, at 10, col. 3.

CONCLUSION

For the reasons stated, a writ of certiorari should be granted to review the judgment and opinion of the United States Court of Appeals for the Fifth Circuit.

Respectfully submitted,

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October 29, 1974

APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

October Term, 1972

No. 72-2251

D. C. Docket No. CA-70-B-115

EPIFANIO REYES, Individually and as next Friend of Anita Reyes, a minor, *Plaintiff-Appellee,*

versus

WYETH LABORATORIES, a Division of American Home Products Corporation, a Delaware Corporation, *Defendant-Appellant.*

Appeal from the United States District Court for the Southern District of Texas

Before BROWN, Chief Judge, and WISDOM and AINSWORTH, *Circuit Judges.*

JUDGMENT

This cause came on to be heard on the transcript of the record from the United States District Court for the Southern District of Texas, and was argued by counsel:

ON CONSIDERATION WHEREOF, It is now here ordered and adjudged by this Court that the judgment of the said District Court in this cause be, and the same is hereby, affirmed;

It is further ordered that defendant-appellant pay to plaintiff-appellee, the costs on appeal to be taxed by the Clerk of this Court.

July 31, 1974

Issued as Mandate

OPINION

[498 F.2d 1264 (5th Cir. 1974).]

Diversity action against defendant which marketed trivalent oral polio vaccine. The United States District Court for the Southern District of Texas, Reynaldo G. Garza, J., entered judgment for plaintiff, and defendant appealed. The Court of Appeals, Wisdom, Circuit Judge, held that where defendant which marketed unavoidably unsafe trivalent oral polio vaccine failed to provide parents of infant with either warning of risk of individualized medical judgment that treatment was necessary and desirable for infant, defendant was liable for failing to market its unavoidably unsafe product in such a way as to warrant [sic] parents of unreasonably dangerous condition.

Affirmed.

* * * * * *

Loyd E. Bingham, Jr., San Antonio, Tex., Eberle, Berlin, Kading, Turnbow & Gillespie, R. B. Kading, Jr., William J. McKlveen, Boise, Idaho, for defendant-appellant.

Daniel R. Murray, Chicago, Ill., for American Academy of Pediatrics, amicus curiae.

William J. Curran, Boston, Mass., for Conference of State and Territorial Epidemiologists, amicus curiae.

Rafael H. Flores, J. Perry Jones, McAllen, Tex., for plaintiff-appellee.

Before Brown, Chief Judge, and Wisdom and Ainsworth, Circuit Judges.

Wisdom, Circuit Judge:

This products liability case raises significant questions concerning the scope of a drug manufacturer's duty to warn ultimate consumers of dangers inherent in his product.

In May 1970, slightly more than two weeks after she had received a dose of Wyeth Laboratories' oral polio vaccine, eight-month-old Anita Reyes was diagnosed as having paralytic poliomyelitis. Epifanio Reyes, Anita's father, filed suit against Wyeth Laboratories, alleging that the live polio virus in the vaccine had caused Anita's polio and that Wyeth was liable for her injuries because it had failed to warn her parents of this danger. Wyeth contends that it is not liable for Anita Reyes's injuries under the products liability law of Texas. In addition, Wyeth raises numerous procedural and evidentiary questions. The case was tried to a jury. The jury answered special interrogatories (see Appendix A) and returned a verdict in favor of Reyes against Wyeth for the sum of $200,000.

I.

Twenty or thirty years ago poliomyelitis was a dread disease that especially attacked the very young. In 1952 alone, there were 57,879 reported cases of polio in the United States; 21,269 of these resulted in crippling paralysis to the victims. By 1970, when Anita Reyes contracted polio, the number of those stricken by polio had diminished dramatically; she was one of just 33 individuals to be afflicted during that year.[1] Credit for this precipitous decline must go primarily to the medical researchers who discovered the viral nature of the disease, and were able to isolate and reproduce the virus in an inactivated or an attenuated form. See Appendix B. But credit for this remarkable achievement must also be given to such laboratories as Wyeth, which processed the polio vaccine, and to massive federal-state public health programs for the administration of the vaccine.

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[1] These statistics are drawn from official reports of the United States Public Health Service. See Morbidity and Mortality, Weekly Reports, Vol. 10, No. 53, Table 2, Page 4. (October 1962); Morbidity and Mortality, Weekly Reports, Vol. 19, No. 3, Table 2, Page 4 (August 1971).

On May 8, 1970, Anita Reyes was fed two drops of Sabin oral polio vaccine by eye-dropper at the Hidalgo County Department of Health clinic in Mission, Texas. The vaccine was administered to Anita by a registered nurse; there were no doctors present. Mrs. Reyes testified that she was not warned of any possible danger involved in Anita's taking the vaccine. Mrs. Reyes has a seventh grade education, but her primary language is Spanish. She signed a form releasing the State of Texas from "all liability in connection with immunization". The form contained no warning of any sort, and it is apparent from her testimony that she either did not read the form or lacked the linguistic ability to understand its significance. About fourteen days after the vaccine was administered, Anita Reyes became ill. On May 23, 1970, she was admitted to the McAllen (Texas) General Hospital, where her disease was diagnosed as Type I paralytic poliomyelitis. See Appendix B, foonote 59. As a result of the polio, at the time of trial Anita was completely paralyzed from the waist down, her left arm had become atrophied, and she was unable to control her bladder or bowel movements.

The vaccine given Anita Reyes in the Mission clinic on May 8, 1970 was part of a "lot", No. 15509, prepared by Wyeth.[2] Lot No. 15509 was trivalent oral polio vaccine that Wyeth had titered (mixed) from Types I, II, and III monovalent vaccine provided by Pfizer, Ltd. In response to an order placed by the Texas State Department of Health on December 23, 1969, Wyeth shipped 3500 vials of Lot No. 15509 vaccine to the State Health Department which in turn transferred 400 vials to the Hidalgo County

[2] The actual titering was performed by Wyeth Laboratories, Inc., a separately incorporated subsidiary of American Home Products, Inc. After this mixing process was complete the vaccine was shipped to American Home Products' unincorporated Wyeth Laboratories Division for distribution. Since both the division and the subsidiary are affiliates of appellant American Home Products, Inc. they are referred to interchangeably as "Wyeth" in the text.

Health Department. The jury found that vaccine from one of these vials was given to Anita Reyes. Included with every vial, each of which contained ten doses of vaccine, was a "package circular" provided by Wyeth which was intended to warn doctors, hospitals, or other purchasers of potential dangers in ingesting the vaccine. Mrs. Lenore Wiley, the public health nurse who administered the vaccine to Anita Reyes, testified that she had read the directions on this package insert, but that it was not the practice of the nurses at the Mission Health Clinic to pass on the warnings to the vaccinees or to their guardians. She testified that she gave Mrs. Reyes no warning before she administered the vaccine to Anita.

On October 7, 1970, Epifanio Reyes, individually and as next friend of his minor daughter, brought this action on theories of strict products liability, breach of warranty, and negligence. In his complaint he alleged that his daughter had contracted polio from the live virus in Wyeth's vaccine, and that Wyeth's failure to warn him or his wife that this might occur rendered it liable for Anita's injuries. Wyeth's main line of defense was that Anita's polio was not vaccine-induced at all. Wyeth produced experts who characterized virus isolated from a specimen of stool taken from Anita on the day after she was admitted to the hospital as "probably wild". This probability was increased, according to epidemiological testimony adduced on Wyeth's behalf,[3] by the fact that there was a polio "epidemic" in Hidalgo County at the time Anita fell ill. In effect, the jury rejected these theories in rendering a verdict for Reyes.

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[3] "Epidemiology", the field of expertise of a number of Wyeth's experts, was defined in the defendant's trial brief as a "specialized field of medicine dealing with public health", which is "based on the observation of the occurrence of disease and thereafter, by statistical methods trying to arrive at a conclusion as to the possible source of the disease".

Wyeth asserts more than a score of separate grounds for reversal, each accompanied by extensive argument and citation. We have considered all of these contentions, but in this opinion we shall address only those challenges which we regard as raising substantial questions.

II.

We turn first to the substantive issues raised by this appeal. Our inquiry is bounded by the jury's finding that Wyeth's vaccine was the producing cause of Anita Reyes's polio, and by those principles of products liability law we conclude would be applied by the courts of Texas. Erie R. R. Co. v. Thompkins, 1938, 304 U.S. 64, 58 S.Ct. 817, 82 L.Ed. 1188.

The jury's finding that the Wyeth vaccine was responsible for Anita Reyes's polio is less a conclusion than a starting point. Texas courts may hold manufacturers of products which harm consumers liable for the injuries, but, of course, manufacturers are not insurers.[4] Texas courts recognize both tort and warranty theories of products liability.[5] This case was tried, briefed, and argued on appeal entirely on the tort theory of strict liability. Thus the differences between the two approaches,[6] and whatever

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[4] Gravis v. Parke-Davis & Co., Tex.Civ.App. 1973, 502 S.W.2d 863, 868-869; Cudmore v. Richardson-Merrell, Inc., Tex.Civ.App. 1965, 398 S.W.2d 640, 644, writ ref. n. r. e., cert. denied, 1967, 385 U.S. 1003, 87 S.Ct. 705, 17 L.Ed.2d 542.

[5] See Borel v. Fibreboard Paper Products Corporation, 5 Cir. 1973, 493 F.2d 1076; reh. denied, 1973.

[6] Strict liability is "hardly more" than warranty stripped of its contractual trappings, Greeno v. Clark Equipment Co., N.D. Ind. 1965, 237 F.Supp. 427, 429. But if strict liability has supplanted warranty as the dominant doctrine, Grinnell v. Charles Pfizer & Co., Cal.Ct.App.1969, 274 Cal.App.2d 424, 79 Cal. Rptr. 369, 373, the outcome of product liability actions, especially where drugs are involved, does not appear to be a result of which theory is relied upon by the parties. See Davis v. Wyeth Laboratories, 9 Cir. 1968, 399 F.2d 121, 126; Merrill, Compensation for Prescription Drug Injuries, 59 Va.L.Rev. 1, 31 (1973).

contractual trappings of warranty have not been destroyed with the crumbling of the citadel of privity,[7] need not detain us. Rather, we turn to the theory of strict products liability as embodied in Section 402A of the Restatement (Second) of Torts (1965),[8] and approved by the Supreme Court of Texas in McKisson v. Sales Affiliates, Tex.Sup.Ct. 1967, 416 S.W.2d 787.[9]

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[7] See Prosser, The Assault Upon the Citadel (Strict Liability to the Consumer), 69 Yale L.J. 1099, (1960); Prosser, The Fall of the Citadel (Strict Liability to the Consumer) 50 Minn.L.Rev. 791 (1966).

[8] § 402A. Special Liability of Seller of Product for Physical Harm to User or Consumer

(1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if

(a) the seller is engaged in the business of selling such a product, and

(b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.

(2) The rule stated in Subsection (1) applies although

(a) the seller has exercised all possible care in the preparation and sale of his product, and

(b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

[9] The principle that sellers of food and drink for human consumption should be held to a high level of responsibility for any "corruption" in their wares is of medieval origin. Restatement of Torts, (Second) Section 402A, comment b; Prosser, The Assault Upon the Citadel (Strict Liability to the Consumer), 69 Yale L.J. 1099, 1103, (1960). There is no point in rehashing the history of the products liability doctrine. See, e.g., Professor Prosser's articles cited in Note 7, *supra;* Ray, Wade, P. Keeton, Noel, R. Keeton, and Whitmore, Products Liability—A Symposium, 19 Sw.L.J. 1 (1965); Traynor, note 11, infra; Greenman v. Yuba Power Products, Inc., Cal.Sup.1963, 59 Cal.2d 57, 27 Cal.Rptr.

Basically, Section 402A subjects to liability the seller or manufacturer of a product sold "in a defective condition unreasonably dangerous" to an ultimate user or consumer whose person or property is physically harmed by the product.[10] Moreover, one who places defective goods in the stream of commerce will be liable "to the user or consumer even though he has exercised all possible care in the preparation and sale of the product". Restatement (Second) of Torts, Section 402A, comment a. Yet imposition of liability is by no means automatic; the elements tacit or explicit in Section 402A's mandate must be demonstrated to the trial court's satisfaction before the burden of the consumer's loss will be imposed on the seller of the product:

> The plaintiff is faced with an arduous burden of proof. He must prove that: 1) the product in question was defective; 2) the defect existed at the time the products left the hands of the defendant; 3) that because of the defect the product was unreasonably dangerous to the user or consumer (plaintiff); 4) that the consumer was injured or suffered damages; 5) and that the defect (if proved) was the proximate cause of the injuries suffered.

Gravis v. Parke-Davis & Co., Tex.Civ.App.1973, 502 S.W.2d 863, 868. Although we do not embrace Gravis as the all-inclusive embodiment of Texas products liability law,

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697, 377 P.2d 897; Escola v. Coca Cola Bottling Co., Cal.Sup.1944, 24 Cal.2d 453, 150 P.2d 436, 440 (Traynor, J., concurring). For recent articles on the Texas law of products liability, see Holford, The Limits of Strict Liability for Product and Manufacture, 52 Tex.L.Rev. 81 (1973); Freedman, The Texas Politics of Today's Products Liability, 5 St.Mary's L.J. 1 (1973); Schattman, A Cause of Action for the Allergic Consumer, 8 Hou.L.Rev. 827 (1971).

[10] Although the Restatement speaks in terms of "sellers", manufacturers of defective products are also swept within its ambit, even where, as here, another party performs the actual transfer of the offending product. See Section 402A, Comment f.

the framework it provides suggests a useful analysis for the issue of Wyeth's liability here.

All five elements, however, which constitute the Gravis requirements need not be discussed here. There can be no question that Anita Reyes was injured, so the fourth element is not in issue. Nor is the second, since the defect alleged, failure to warn by the manufacturer, is by definition the *manufacturer's* dereliction. Moreover, to find that the plaintiff proved the first element is to conclude that he proved the third, for properly understood, "defective condition" has no meaning independent of "unreasonably dangerous"; the two terms are essentially synonymous.[11] Thus if a product is unreasonably dangerous as marketed, the manufacturer may be held liable for injuries proximately caused by what he has produced, whether or not it was manufactured exactly as intended, that is without a production "defect".[12] We do not understand this approach to dispense with the principle that to prompt liability a product must reach the consuming public in a "defective condition". Rather, by rephrasing the defectiveness requirement in terms of "unreasonable danger", it becomes clear that the circumstances of marketing themselves can amount to a defect; the defect can be extrinsic to the product. All that we need determine here,

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[11] Borel v. Fibreboard Paper Products Corp., 5 Cir. 1973, 493 F.2d 1076, 1087; Wade, Strict Tort Liability of Manufacturers, 19 Sw.L.J. 5, 14-15 (1965); Keeton Product Liability and the Meaning of Defect, 5 St.Mary's L.J. 30, 32 (1973). Justice Traynor goes still further. He has concluded that there is no single satisfactory definition of "defect" which will bear universal application. See Traynor, The Ways and Meanings of Defective Products and Strict Liability, 32 Tenn.L.Rev. 363, 367 (1965).

[12] See, e.g., Alman Bros. Farm and Feed Mill, Inc. v. Diamond Laboratories, Inc., 5 Cir. 1971, 437 F.2d 1295, 1302; Ross v. Up-Right, Inc., 5 Cir. 1968, 402 F.2d 943, 946; Helene Curtis Industries, Inc. v. Pruitt, 5 Cir. 1967, 385 F.2d 841, 855, cert. denied, 1968, 391 U.S. 913, 88 S.Ct. 1806, 20 L.Ed. 2d 652.

then, is first, whether the vaccine was unreasonably dangerous, and second, whether the showing of proximate causation was sufficient under Texas law.

a) Unreasonable Danger and the Duty to Warn

We begin the inquiry by asking whether the vaccine was unreasonably dangerous, that is, in a defective condition when Anita Reyes received it. It is clear, of course that the vaccine was not itself defective. Wyeth Vaccine Lot No. 15509 was exactly what its makers [13] and the Texas public health authorities intended it to be: trivalent live-virus Sabin oral polio vaccine. The live virus which the jury concluded caused Anita's poliomyelitis was not inadvertently included in the mixture.[14] Indeed, it is the presence of the living but attenuated Type I, II, and III viruses which makes the Sabin vaccine so effective [See Appendix B].

Although the living virus in the vaccine does not make the vaccine defective, it does make it what the Restatement calls an "unavoidably unsafe product", one which cannot be made "safe" no matter how carefully it is manufactured. Such products are not necessarily "*unreasonably* dangerous", for as this Court has long recognized in wrestling with product liability questions, many goods

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[13] In a strict sense, Wyeth did not "make" or manufacture the vaccine which caused Anita Reyes's polio. The lot of trivalent vaccine was "titered" or mixed from separate strains of Type I, Type II, and Type III monovalent vaccines manufactured by Pfizer, Ltd. In the context of this case, however, we do not believe, nor did Wyeth argue, that this fact in any way affects its liability.

[14] Thus this action does not involve "defective" vaccine in the same sense as did Gottsdanker v. Cutter Laboratories, Cal.App. 1960, 182 Cal.App.2d 602, 6 Cal.Rptr. 320, an action in which the producer of Salk "killed virus" vaccine was held liable for the plaintiff's poliomyelitis caused by live virus inadvertently present in its vaccine.

possess both utility and danger. See, e.g., Ross v. Up-Right, Inc., 5 Cir. 1968, 402 F.2d 943, 946; Helene Curtis Industries, Inc. v. Pruitt, 5 Cir. 1967, 385 F.2d 841, 850, cert. denied, 1968, 391 U.S. 913, 88 S.Ct. 1806, 20 L.Ed.2d 652. Rather, in evaluating the possible liability of a manufacturer for injuries caused by his inevitably hazardous products, a two-step analysis is required to determine first, whether the product is so unsafe that marketing it at all is "unreasonably dangerous per se", and, if not, whether the product has been introduced into the stream of commerce without sufficient safeguards and is thereby "unreasonably dangerous as marketed."[15] In either case, the applicable standard, as formulated in the Restatement, is as follows: In terms of the user's interests, a product is "unreasonably dangerous" only when it is "dangerous to an extent beyond that contemplated by the ordinary consumer";[16] or, to phrase it in terms of the seller's responsibility, "so dangerous that a reasonable man would not sell the product if he knew the risk involved". See Borel v. Fibreboard Paper Products Corp., 5 Cir. 1973, 493 F.2d 1076, 1088; Helene Curtis Industries, Inc. v. Pruitt, 385 F.2d at 850; Wade, Strict Tort Liability of Manufacturers, 19 Sw.L.J. 5, 15 (1965).

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[15] This "per se as marketed" distinction has been suggested by Dean Keeton. See e.g., Keeton, Products Liability—Inadequacy of Information, 48 Tex.L.Rev. 399, 406 (1970); Keeton, Products Liability and Meaning of Defect, 5 St. Mary's L.J. 30, 38 (1973).

[16] Comment i to Section 402A elaborates:

> I. *Unreasonably dangerous.* The rule stated in this Section applies only where the defective condition of the product makes it unreasonably dangerous to the user or consumer. Many products cannot possibly be made entirely safe for all consumption, and any food or drug necessarily involves some risk of harm, if only from over-consumption. . . . The article sold must be dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics.

In determining whether placing a commodity on the market is "unreasonably dangerous per se", the reasonable man standard of the Restatement becomes the fulcrum for a balancing process in which the utility of the product properly used is weighed against whatever dangers of harm inhere in its introduction into commerce. Obviously, use of an unavoidably unsafe product always presents at least a minimal danger of harm, but only if the potential harmful effects of the product—both qualitative and quantitative—outweigh the legitimate public interest in its availability will it be declared unreasonably dangerous per se and the person placing it on the market held liable.[17] Applying this standard here, the scales must tip in favor of availability. The evil to be prevented—poliomyelitis and its accompanying paralysis—is great. Although the danger that vaccinees may contract polio is qualitatively devastating, it is statistically miniscule. On balance then, marketing the vaccine is justified despite the danger.

Since Sabin oral polio vaccine is not "unreasonably dangerous per se", we move to the second step of our analysis to determine whether it is "unreasonably dangerous as marketed", for to conclude that the maker of an unavoid-

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[17] Professor Wade suggests a rather more complex calculus, with no fewer than seven variables:

> Factors involved in making this determination include, among others, the following: (1) the usefulness and desirability of the product, (2) the availability of other and safer products to meet the same need, (3) the likelihood of injury and its probable seriousness, (4) the obviousness of the danger, (5) common knowledge and normal public expectation of the danger (particularly for established products), (6) the avoidability of injury by care in use of the product (including the effect of instructions or warnings), and (7) the ability to eliminate the danger without seriously impairing the usefulness of the product or making it unduly expensive.

19 Sw.L.J. at 17. Without elaborating, we believe that however scrutinized, the oral polio vaccine was not "unreasonably dangerous per se", for the reasons marshaled in the text

ably unsafe product did not act unreasonably in placing it on the market is not to relieve him of the responsibility to market it in such a way as to prevent unreasonable danger. In the case of a product such as Sabin oral polio vaccine, this translates into a duty to provide proper warnings in selling the product. As comment k to Section 402A instructs, an unavoidably unsafe product is neither defective nor *unreasonably* dangerous if such a product is "properly prepared, and is accompanied by proper directions and warning".[18] Consequently, the Restatement requires a seller who has reason to believe that danger may result from a particular use of his product to provide adequate warning of the danger in order that the product's potential

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[18] Comment k provides:

> k. *Unavoidably unsafe products.* There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

for harm may be reduced. Failure to give such a warning when it is required will itself present a "defect" in the product and will, without more, cause the product to be "unreasonably dangerous as marketed".[19]

Issue is joined then, on the question whether Wyeth was under a duty to warn the parents of Anita Reyes that there was a possibility, however remote, that she might contract polio from the drug designed to immunize her.

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[19] See Ford Motor Co. v. Russell & Smith Ford Co., Tex. Civ.App.1971, 474 S.W.2d 549, no writ hist.; see also, Rumsey v. Freeway Motor Minimax, Tex.Civ.App.1968, 423 S.W.2d 387, 393, no writ hist. Restatement (Second) of Torts, Section 402A, Comments h and j (1965).

Comment h provides in pertinent part:

> h. A product is not in a defective condition when it is safe for normal handling and consumption. If the injury results from abnormal handling, as where a bottled beverage is knocked against a radiator to remove the cap, or from abnormal preparation for use, as where too much salt is added to food, or from abnormal consumption, as where a child eats too much candy and is made ill, the seller is not liable. Where, however, he has reason to anticipate that danger may result from a particular use, as where a drug is sold which is safe only in limited doses, he may be required to give adequate warning of the danger (see Comment j), and a product sold without such warning is in a defective condition.

Comment j provides:

> j. Directions or warning. In order to prevent the product from being unreasonably dangerous, the seller may be required to give directions or warning, on the container, as to its use. The seller may reasonably assume that those with common allergies, as for example to eggs or strawberries, will be aware of them, and he is not required to warn against them. Where, however, the product contains an ingredient to which a substantial number of the population are allergic, and the ingredient is one whose danger is not generally known, or if known is one which the consumer would reasonably not expect to find in the product, the seller is required to give warning against it, if he has knowledge, or by the application of reasonable, developed human skill and foresight should have knowledge, of the presence of the ingredient and the danger.

If such a duty existed, the vaccine was "defective" and unreasonably dangerous as marketed, for such cautions as Wyeth advanced did not, and were not intended to, reach the Reyes family. See Davis v. Wyeth Laboratories, Inc., 9 Cir. 1968, 399 F.2d 121, 129.

Wyeth does not deny that its vaccine is "unavoidably unsafe", or contend that it was unaware of the danger. Rather, the appellant contends that if it had a duty to warn at all, that duty was discharged by the warning contained on the package insert which accompanied the vials of vaccine sold to the Texas State Department of Health. This is so, Wyeth asserts, because the Sabin trivalent oral polio vaccine in issue here is a "prescription drug", and those who prepare such drugs are not required to warn the ultimate consumer. If the warning to the dispensing physician or authorities (here the Texas and Hidalgo County Public Health Departments) was adequate, Wyeth is not liable for any harm caused by the vaccine. Resolution of these contentions is crucial; Wyeth concedes in its brief that "[s]ince it is undisputed that Wyeth did not warn Reyes, but only the Texas State Department of Health, a finding that the vaccine was not a prescription drug establishes as a matter of law the defectiveness of the vaccine for purposes of a prima facie case in strict products liability."

We cannot quarrel with the general proposition that where *prescription* drugs are concerned, the manufacturer's duty to warn is limited to an obligation to advise the prescribing physician of any potential dangers that may result from the drug's use.[20] This special standard for prescription drugs is an understandable exception to the Restatement's general rule that one who markets goods

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[20] See, e.g., Basko v. Sterling Drug, Inc., 2 Cir. 1969, 416 F.2d 417, 426; Davis v. Wyeth Laboratories, 9 Cir. 1968, 399 F.2d 121, 130; Merrill, Compensating for Prescription Drug Injuries, *supra* note 6, at 91. This approach has been adopted by at least one Texas court. See, Gravis v. Parke-Davis, Inc., Tex.Civ.App.1973, 502 S.W.2d 863, 870.

must warn foreseeable ultimate users of dangers inherent in his products. See Restatement (Second) of Torts, Section 388 (1965). Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative. Pharmaceutical companies then, who must warn ultimate purchasers of dangers inherent in patent drugs sold over the counter, in selling prescription drugs are required to warn only the prescribing physician, who acts as a "learned intermediary" between manufacturer and consumer.[21]

Although there is no question that Sabin oral vaccine is licensed for sale only as a prescription drug,[22] the district court, in its charge to the jury, noted that the vaccine was not administered as a prescription drug at the Mission Clinic. The court charged: "if you [the jury] find that a warning should have been given, the warning had to be given to Anita and her parents, not to Mrs. Wiley, that Public Health nurse, somebody else . . . The ultimate consumer is the one that had to be warned." The district court apparently based this instruction on the leading federal case in the area, Davis v. Wyeth Laboratories, 9 Cir. 1968, 399 F.2d 121. In *Davis,* the plaintiff had allegedly contracted polio from Wyeth oral vaccine distributed at a public clinic. The Ninth Circuit held that where no indi-

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[21] See, Schenebeck v. Sterling Drug, Inc., 8 Cir. 1970, 423 F.2d 919, 922; Davis v. Wyeth, *supra* note 20, 399 F.2d at 130; Sterling Drug, Inc. v. Cornish, 8 Cir. 1966, 370 F.2d 82, 85; Gravis v. Parke-Davis & Co., *supra,* note 20, 502 S.W.2d at 870, 56 Geo.L.J. 1016, 1018 (1968).

[22] See, Title 42 U.S.C. § 262(a); 42 C.F.R. §§ 73.200-73.240, 73.1020-73.1028.

vidualized medical judgment intervenes between the manufacturer of a prescription drug and the ultimate consumer, "it is the responsibility of the manufacturer to see that warnings reach the consumer, either by giving warning itself or by obligating the purchaser to give warning." 399 F.2d at 131. Where there is no physician to make an "individualized balancing . . . of the risks", the Court reasoned, the very justification for the prescription drug exception evaporates. Thus, as in the case of patent drugs sold over the counter without prescription, the manufacturer of a prescription drug who knows or has reason to know that it will not be dispensed as such a drug must provide the consumer with adequate information so that he can balance the risks and benefits of a given medication himself. Moreover, just as the manufacturer cannot make this choice for its ultimate consumers, it cannot allow its immediate purchaser to choose for them. In sum, then, the manufacturer is required to warn the ultimate consumer, or to see that he is warned. 399 F.2d at 131.

Wyeth does not resist the Ninth Circuit's holding in *Davis*, but asserts that the instant case can be distinguished on four grounds. First, the appellant argues, Davis received his vaccine during a mass immunization program, whereas Anita Reyes ingested her vaccine at her parents' request. Second, Wyeth stresses the fact that Davis received his vaccine from a pharmacist, but Reyes' was administered by a public health nurse. Third, Wyeth's active participation in the mass immunization program involved in the *Davis* case is contrasted to its relatively passive role here. Finally, Wyeth urges that unlike the situation in *Davis*, here it had no knowledge that the vaccine would not be administered as a prescription drug.

None of these asserted grounds for distinguishing *Davis* justifies a different result here. The first two arguments are admittedly distinctions between *Davis* and the instant controversy, but they have no bearing on the *rationale* of the *Davis* opinion. Whether vaccine was received during

a mass immunization or an on-going program, whether it was administered by nurse or pharmacist, it was, in both these cases, dispensed without the sort of individualized medical balancing of the risks to the vaccinee that is contemplated by the prescription drug exception. The third and fourth asserted bases for distinguishing *Davis* from this case are essentially the same: Wyeth took no active part in the vaccination process here, and did not know that its vaccine would be dispensed without procedures appropriate for distribution of prescription drugs.

Were we to conclude that Wyeth neither knew nor had reason to know that its vaccine would be dispensed without prescription drug safeguards, we might be required to hold that the *rationale* in *Davis* is inapplicable here. But Wyeth had ample reason to foresee the way in which its vaccine would be distributed. A drug manufacturer is held to the skill of an expert in his field, and is presumed to possess an expert's knowledge of the arts, materials, and processes of the pharmaceutical business.[23] Included in such expertise must be a familiarity with practices and knowledge common in the drug industry as to distribution and administration of pharmaceutical products.

Neal Nathanson, Professor of Epidemiology at the Johns Hopkins University School of Public Health and a witness for Wyeth testified that it was common knowledge in the drug industry that "a great majority" of vaccinees receive their Sabin vaccine in mass administrations or county clinics manned at least in part by volunteers. Moreover, Dr. Nathanson agreed that it was well known that such clinics were stocked primarily by sale of vaccine to state health departments. These clinics, as Wyeth must be presumed to know, dispense Sabin vaccine to all comers in an

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[23] See, e.g., Wright v. Carter Products, Inc., 2 Cir. 1957, 244 F.2d 53; Johnston v. Upjohn Co., Mo.Ct.App.1969, 442 S.W.2d 93, 96; Bine v. Sterling Drug Co., Mo.Sup.Ct.1968, 422 S.W.2d 623, 628; 2 F. Harper & F. James, The Law of Torts § 28.4 (1956); 5 San Diego L.Rev. 422, 427, n. 18 (1968).

"assembly line" fashion; there is often neither time nor personnel to make an "individualized medical judgment" of the vaccinee's needs or susceptibilities. See Davis v. Wyeth, *supra,* 399 F.2d at 131; 56 Geo.L.J. 1016, 1017 (1968); 5 San Diego L.Rev. 422, 428 (1968).

Viewed in this light, the present controversy, however it differs from *Davis* factually, invites application of the *Davis* principles, and the conclusion that Wyeth was under a duty to warn Anita Reyes's parents of the danger inherent in its vaccine. Wyeth knew or had reason to know that the vaccine would not be administered as a prescription drug, and therefore was required to warn foreseeable users, or see that the Texas Department of Health warned them. See Davis v. Wyeth, *supra,* 399 F.2d at 131; cf. Helene Curtis Industries v. Pruitt, *supra,* 385 F.2d at 861. Wyeth's failure to warn was a breach of its duty and made the vaccine "defective"—hence "unreasonably dangerous" —as marketed.

Before moving to a consideration of causation, we pause to analyze two possible arguments, one raised by Wyeth and one not, which appear to add further conceptual problems in the "duty to warn" area.

The first may be disposed of quickly. Wyeth contends that whatever its duty to warn, Mrs. Reyes assumed the risk that her daughter might contract polio, or effectively released Wyeth, by signing a "release" purporting to excuse the State of Texas from liability. Wyeth does not explain how signing a form releasing the State could excuse Wyeth from performing a duty to warn imposed on it by law, other than to cite the "unity of release" rule, apparently under the assumption that the State of Texas was its agent. Since we decline to adopt the district court's conclusion that Texas was the agent of Wyeth in administering the vaccine, we need not consider Wyeth's contention that the release signed by Mrs. Reyes also applied to it. Moreover, although we agree that assumption of risk is a proper

defense to a product liability action in Texas (see Borel v. Fibreboard Paper Products Corp.) one cannot assume a risk of which he is unaware. Shamrock Fuel & Oil Sales Co. v. Tunks, Tex.Sup.1967, 416 S.W.2d 779, 786 and n. 8. Since Mrs. Reyes was not cognizant of the danger inherent in the vaccine, she could not have assumed the risk of its use.

Somewhat more troubling is a line of Texas cases involving unusual allergic reactions to potentially dangerous products sold without a warning. These decisions may be read for the proposition that only if the product, properly prepared, will harm a substantial number of people will the manufacturer be held liable for his failure to warn. See C. A. Hoover & Son v. O. M. Franklin Serum Co., Tex.Sup. 1969, 444 S.W.2d 596, 598; Alberto-Culver Co., v. Morgan, Tex.Civ.App.1969, 444 S.W.2d 770, 776-777, writ ref. n. r. e.; Cudmore v. Richardson-Merrell, Inc., Tex.Civ.App. 1966, 398 S.W.2d 640, 644,[24] writ ref. n. r. e., cert. denied, 1967, 385 U.S. 1003, 87 S.Ct. 705, 17 L.Ed.2d 542.

Essentially these are foreseeability cases; the element they would require to invoke strict liability doctrines is foreseeability. In these cases, the manufacturer not only marketed the unavoidably unsafe product without adequate warning and with the knowledge that it was inherently dangerous, but the danger to any individual consumer was sufficiently significant and knowable that (1) the manufacturer was cognizant of a need to warn so as to prevent injury and (2) the consumer might or could have altered his conduct in such a way as to lessen or avoid the danger. This ancipital coin of foreseeability is the currency of these Texas cases. What they seek to avoid is the imposi-

[24] There is considerable and respectable authority at variance with the Texas position that immunizes a drug manufacturer from liability to an idiosyncratic consumer. See, e.g., Davis v. Wyeth Laboratories, *supra* note 20, 399 F.2d at 129; Sterling Drug, Inc. v. Cornish, *supra* note 21, 370 F.2d at 85.

tion of liability for "abreactions", hypersensitive allergic reactions so unique that the class of persons *exposed* to the risk is miniscule. See Cudmore v. Richardson-Merrell, Inc., 398 S.W.2d at 644. In such cases, warnings would be meaningless, since the manufacturer can convey nothing meaningful to the allergic consumer unless the latter knows he has the allergy. Without such knowledge, the consumer is apt to assume that he is not a member of the minute susceptible class and to disregard the warning. See Alberto-Culver Co. v. Morgan, 444 S.W.2d at 777. Thus with the utility of warning limited and the susceptible class minute, the manufacturer is not required to foresee that anyone will suffer an allergic reaction to his product, and is not held liable.

To the instant analysis, these principles present no dilemma, for the effect of the Sabin oral vaccine upon those who contract polio from it cannot fairly be styled an "abreaction".[25] Although the danger of vaccine-induced polio to any one individual is small, the risk appears to be distributed evenly among that substantial segment of the population that is not naturally immune to polio. This is so because the behavior of polio virus in those who contract the disease seems to suggest more a reversion to virulence by the virus than a sensitivity in the vaccinee. Thus, if an individual is a member of the significant susceptible class, and his case should be one of those rare instances in which the vaccine strain reverts to virulence, he may contract polio. This is not a case like *Cudmore*, then, where the "appellant belongs to a class of people not appreciable in number who are allergic to the drug," and in which a warning would have been futile. 398 S.W.2d at 644. Rather,

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[25] For a more detailed discussion of various types of allergic reactions, and their legal significance, see, Merrill, Compensating for Prescription Drug Injuries, 59 Va.L.Rev. 1 (1973); Schattman, A Cause of Action for the Allergic Consumer, 8 Houston L.Rev. 827 (1971); Rheingold, Products Liability—The Ethical Drug Manufacturer's Liability, 18 Rutgers L.Rev. 947 (1964).

proper warnings here would be addressed to a sizeable group and would be designed to alert each of its members that although the incidence of vaccine-induced polio is minute, he does belong to a substantial class, an unpredictible few of which could contract polio from the vaccine. In light of such factors, the Texas "abreaction" cases cannot dilute Wyeth's duty to warn here. This view coincides with the objective of Section 402A to protect the consumer by *his* standards of reasonableness in determining the manufacturer's duty.

b) Proximate Cause

Having concluded that Wyeth had a duty to warn Anita Reyes, and that, dispensed without a warning, the vaccine was unreasonably dangerous, we now turn to Wyeth's objections to the trial court's not instructing the jury and not submitting an interrogatory on the issue of "proximate cause".

As Wyeth correctly contends, there are two causation issues in most product liability cases. The first is that of "producing cause": Was the defendant's product the cause-in-fact of the plaintiff's injuries? More specific is the question posed under the rubric of proximate causation: Did the plaintiff's injuries result from the alleged "defect" in the defendant's product? Unless the jury is given an opportunity to pass upon both issues, Wyeth urges, the plaintiff has not made out a prima facie case of product liability. If Wyeth is correct, reversal is required, for the trial judge made it clear that he did not believe proximate cause to be an issue in this controversy, and neither instructed the jury nor submitted an interrogatory on the question.[26] We cannot concur in Wyeth's premise,

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[26] A colloquy on requested instructions between two attorneys for Wyeth and the court make the court's position on the need to prove proximate cause clear:

MR. KADING: Then we believe that there should be an interrogatory between number five and number six which makes

however. The submission of interrogatories accompanying a general verdict is within the discretion of the trial court.[27] Moreover, although an instruction on proximate cause is appropriate in most products liability cases, a jury finding on the question was not required here.

As a general proposition, both Texas Courts and this Court have required that the plaintiff in a product liability suit prove not only that his injuries were caused by the defendant's product, but that they resulted from an alleged defect in the product.[28] Leading commentators have con-

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this a matter of proximate cause. In other words, to the effect asking the jury to find whether or not the failure to warn was proximate cause of the consequences to this child in view of the fact that even with warning they may have proceeded with immunization, and in fact did so even after immunization here. And I suppose for the purposes of the record I ought to ask the court to in effect resubmit interrogatories that we submitted to the court before.

MR. MCKLVEEN: And I think as to interrogatory number two dealing with producing cause rather than causal cause the jury should be instructed that they should find—have to find first—the product was not fit for the purpose for which it was intended in order to get into proximate cause rather than producing cause.

THE COURT: Well, I have already stated at the beginning what my feelings are in this case, that if there was a risk, if she did get it from the vaccine, and you all failed to warn them about the risk so that they could make a choice, that you are liable regardless. And I think I have enough answers here.

MR. FLORES: We have no objections.

THE COURT: I wouldn't mind giving the question of proximate cause but I don't think it is necessary and you all tell me that you don't want it in there.

[27] The submission of interrogatories accompanying a verdict is sanctioned by Fed.R.Civ.P. 49(b).

The trial judge's decision to submit the issues to the jury pursuant to Rule 49(b) is within his discretion, and will be reversed only upon a clear showing of abuse. See Abernathy v. Southern Pacific Co., 5 Cir. 1970, 426 F.2d 512.

[28] E.g., Technical Chemical Co. v. Jacobs, Tex.Sup.1972, 480 S.W.2d 602, 605; Kritser v. Beech Corp., 5 Cir. 1973, 479 F.2d 1089, 1091.

curred.[29] Yet the rule in Texas that proximate cause must be specifically proved in products liability cases is not immutable. In some circumstances, proximate cause may be inferred as a matter of law or as a matter of fact. Procter & Gamble Mfg. Co. v. Langley, Tex.Civ.App.1967, 422 S.W.2d 773, writ dismissed, want of jurisdiction. In other cases, an instruction on producing cause which omits a consideration of proximate cause may be sufficient. C. A. Hoover and Son v. O. M. Franklin Serum Co., Tex.Sup. 1969, 444 S.W.2d 596, 598. We believe, in light of the holding in *Hoover* and crucial dicta in Technical Chemical Co. v. Jacobs, Tex.Sup.1972, 480 S.W.2d 602, that to have omitted a specific proximate cause instruction here was not reversible error.

Hoover was an action against a serum manufacturer by the owners of 25 Hereford calves which had become desperately ill after having been innoculated with the defendant's antibiotic. The trial resulted in a verdict and judgment for the plaintiffs, which was reversed and remanded by the court of civil appeals because the trial court had submitted a special issue on "producing cause" rather than "proximate cause", "and had thus failed to require the element of foreseeability". The Supreme Court of Texas reversed the court of appeals, and held that where, as here, the injury's foreseeability was not in issue, the "producing cause" instruction was sufficient. Much of the Supreme Court's brief opinion is spent in distinguishing the issue presented in *Hoover* from that considered in Cudmore v. Richardson-Merrell, Inc. *Cudmore* required that the jury consider whether the defendant's product was the "proximate cause" of the plaintiff's injuries rather than merely whether it was the "producing cause", since the latter inquiry "omits entirely the element of foreseeability. . . ."

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[29] E.g., Keeton, Products Liability—Inadequacy of Information, 48 Tex.L.Rev. 398, 413 (1970); Wade, Strict Tort Liability of Manufacturers, 19 Sw.L.J. 5, 22, 25 (1965).

The *Hoover* court distinguished *Cudmore* on the ground that it involved an "abreaction" to a "pure drug" and thus foreseeability was a crucial issue. In such a case, a "proximate cause" instruction is required. In *Hoover*, however, all twenty-five innoculated cattle fell ill or died. The jury found that the cause of this widespread illness was not an unforeseeable abreaction. Thus, concluded the Texas Supreme Court, foreseeability was not in issue, and no proximate cause instruction was required.

The *Hoover* rationale is applicable to the instant controversy. Although this is, in a sense, a "pure drug" case like *Cudmore*, as we have pointed out above, it involves no "abreaction". As we have also concluded earlier, foreseeability—both as to the possibility of injuries and the manner of dispensing the drug—is not really in issue. In *Hoover*, "foreseeability" was found by the jury; here it was established as a matter of law. *Hoover* was not, of course, a "failure to warn" case. The defect involved was intrinsic to the serum which felled the plaintiff's cattle, a fact which may differentiate *Hoover* from extrinsic defect cases where the product and defect are separable. See Keeton, Products Liability—Problems Pertaining to Proof of Negligence, 19 Sw.L.J. 26, 33 (1965). Yet language in Technical Chemical Co. v. Jacobs, the recent Texas Supreme Court examination of failure to warn, convinces us that even in this area, a producing cause instruction will suffice in the circumstances of this case.

Technical Chemical involved a suit against the manufacturer of a can of freon which exploded in the plaintiff's hand as he attempted to put its contents into the air conditioning unit of his automobile. It was apparent from testimony adduced at trial that Jacobs, the plaintiff, inadvertently and mistakenly attached a hose from the "high" pressure side of his air conditioning compresser to the can of freon, rather than joining a hose from the "low" pressure side, which was the proper procedure. The can exploded, a possible result which the directions on the can's label did

not mention. Jacobs admitted, however, that *he had not read* the directions on the can's label. In light of this fact, the jury refused to find that Technical Chemical's failure to warn was a cause of Jacobs' injuries.

In affirming the trial verdict, the Supreme Court of Texas held that it was "incumbent upon the plaintiff to secure a jury finding that the faulty labeling was a cause of the injury". This he had not done. 480 S.W.2d at 605. Moreover, a plaintiff who had not read such directions as were provided could hardly expect the court to conclude that the manufacturer's failure to provide further warnings caused his injury as a matter of law.

Although much of the *Technical Chemical* opinion speaks in absolute terms of requiring proof that the defect caused the plaintiff's injuries, it also recognizes how "speculative" testimony in this type of case is likely to be and suggests an alternative approach, a legal "presumption that an adequate warning would have been read". 480 S.W.2d at 606. See Restatement (Second) of Torts, § 402A, comment j. As the court explained:

> Such a presumption works in favor of the manufacturer when an adequate warning is present. Where there is no warning, as in this case, however, the presumption that the user would have read an adequate warning works in favor of the plaintiff user. In other words, the presumption is that Jacobs would have read an adequate warning. The presumption, may, however, be rebutted if the manufacturer comes forward with contrary evidence that the presumed fact did not exist.

480 S.W.2d at 606.

Read together, *Hoover* and *Technical Chemical* suggest a test for cases such as the one now before the Court: Where a consumer, whose injury the manufacturer should have reasonably foreseen, is injured by a product sold without a required warning, a rebuttable presumption will arise that the consumer would have read any warning provided by

the manufacturer, and acted so as to minimize the risks. In the absence of evidence rebutting the presumption, a jury finding that the defendant's product was the producing cause of the plaintiff's injury would be sufficient to hold him liable.

Such a test makes sense in this case. The jury found that the defendant's polio vaccine caused Anita Reyes's polio. Testimony by her mother as to what she would have done, had proper warnings been provided, would have been both speculative and self-serving. Thus we turn to the *Technical Chemical* presumption that a warning, had it been given, would have been heeded. Buttressing the presumption that Mrs. Reyes might have taken preventive steps is the testimony of Reyes' expert, Dr. Ramiro Casso, that some pediatricians in Hidalgo County, at least by the time of trial, had begun administering killed-virus vaccine to infants in order to build up their level of antibodies before feeding them the live-virus drug. Tending to rebut the presumption that Mrs. Reyes would have behaved differently had she been warned was the fact that she twice returned to the Mission Clinic for further doses of vaccine, even after Anita contracted polio. Yet it is patent from her testimony that Mrs. Reyes had not, even then, been informed of the danger of the polio vaccine, and did not in fact understand what medication Anita was to receive.[39] The legal presumption

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[39] On cross-examination, Mrs. Reyes was asked about a card she had signed at the clinic which indicated that she had returned after the onset of Anita's illness:

Q. And did you read that before you signed it?
A. No, I didn't read it. I just signed it.
Q. I notice some other entries. Have you taken Anita back for further immunization since the date of—
A. Yes.
Q. What has she been immunized for or vaccinated for since May 8, 1970?
A. I don't know. They just put it on there.
Q. You just take her and they do it?
A. Yeah. They are the ones that know what they are going to put next.

suggested by the *Technical Chemical* opinion thus operates here to provide the final element necessary to hold Wyeth Laboratories liable for Anita Reyes' poliomyelitis. Aware of its unavoidable dangers and cognizant that it foreseeably would not be dispensed as a prescription drug, Wyeth nonetheless failed to warn Mrs. Reyes that its vaccine could cause polio in some few of the millions receiving the medication. Administered without a warning, the vaccine was "defective", hence unreasonably dangerous. According to the test we have distilled above, we must assume in the absence of evidence to the contrary that Anita's parents would have acted on the warning, had it been given. Perhaps this would have prevented her polio. It unquestionably would have avoided Wyeth's liability.

III.

Having concluded that Wyeth was properly held liable under substantive law, we turn to procedural matters, specifically to Wyeth's objections to the admission or exclusion of various testimony and exhibits, and to its assertion that the evidence was insufficient to support the verdict for the plaintiffs.

(a) The Impeachment of Dr. Fox

Among the medical experts called to testify in Wyeth's behalf was Dr. John D. Fox, Associate Dean and Professor of Epidemiology at the University of Washington School of Public Health. On cross-examination, after Dr. Fox had testified that Type III polio vaccine was less stable than either Type I or Type II, counsel for the plaintiffs attempted to impeach his testimony by reference to an uncertified transcript of an earlier trial in which Dr. Fox had been called as a witness in Wyeth's behalf. There Dr. Fox had testified that Type I polio vaccine was "unstable", with reference to its "antigenic character", and Reyes's counsel attempted to show that this earlier testimony contradicted Dr. Fox's testimony as to Type I's stability here. Upon further inquiry, however, Dr. Fox

was apparently successful in explaining that his previous statement as to Type I's instability dealt only with its "antigenic instability," that is, its tendency to become an "unvaccine-like" strain, whereas his comments on the instability of the Type III virus related to its propensity to cause polio in monkeys or man. On appeal, Wyeth contends that this line of questioning was improper and requires reversal, both because the testimony of an expert cannot be impeached through the use of prior inconsistent statements and because no proper foundation was laid.

We concur in Wyeth's conclusion that the law of Texas governs the conduct of this type of impeachment. See Wright, Law of Federal Courts, § 94 at 412-15.[31] We cannot, however, read the cases cited by the appellant as prohibiting cross-examination of expert witnesses through the use of prior inconsistent testimony. Texas does not bar impeachment of a *lay* witness through the use of testimony given by him at a former trial.[32]

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[31] Professor Charles A. Wright suggests that it may be necessary to look beyond the stark dictates of F.R.Civ.P. 43(a) to determine whether federal or state evidentiary standards ought to be invoked in a given situation. Three types of evidentiary rules exist, he postulates, and the choice between federal and state tests ought be made on the basis of which *type* of rule a given bit of evidence invokes. First are those rules which are of a merely "housekeeping" nature; here federal standards can be applied without hesitation. Next are rules that not merely regulate evidence, but are closely intertwined with the substantive rights of the parties. Here state standards should be honored. Finally, come state evidentiary rules specifically designed to effectuate an extrinsic state policy. So long as the rules are successful in achieving that end, they should be honored. The impeachment of an expert witness challenged here, was, we conclude, so tied to Wyeth's attempt to prove its theory of the case that substantive rights are at stake and Texas impeachment standards must govern. See, C. Wright, Law of Federal Courts, § 94 at 412-415.

[32] Gabel v. Blackburn Operating Corp., Tex.Civ.App.1969, 442 S.W.2d 818, 819, no writ hist.; Flowers v. Central Power and Light Co.; Tex.Civ.App.1958, 314 S.W.2d 373, writ ref. n. r. e.

It is difficult to understand why this impeachment technique ought not be available when the witness is an expert rather than a layman. Indeed, it might be argued that prior inconsistency is a particularly appropriate weapon for attacking expert testimony, since demonstration of the inconsistency is designed not to show that the expert has erred, but that he is *capable* of error. See Cirilo v. Cook Paint and Varnish Co., Tex.Civ.App.1972, 476 S.W.2d 742, 748, writ ref. n. r. e. Not surprisingly, then, Texas courts endorse far-ranging cross-examination generally, and have permitted particularly wide latitude in the interrogation of an adversary's expert. See Davidson v. County of Harris, Tex.Civ.App.1970, 454 S.W.2d 830, 832, writ ref. n. r. e. Thus in Hutson v. State, Tex.Cr.App.1956, 164 Tex.Cr.R. 24, 296 S.W.2d 245, 247-248, the prosecution was permitted to impeach the testimony of a county sheriff as to the defendant's intoxication, by introducing a tape recording (made shortly after the defendant's arrest) in which the sheriff voiced an opinion contrary to that offered at trial. Also permitted in cross-examination of real estate experts has been reference to earlier inconsistent appraisals of land, the value of which is in issue.[33]

A similar standard should apply to expert medical testimony. Wyeth concedes that a cross-examiner may properly inquire whether a medical expert has previously testified on behalf of the party for whom he offers testimony. But, Wyeth urges, any further foray into prior testimonial assertions is forbidden by Texas law. We do not so read the Texas cases. To be sure, no inquiry into the *correctness* of opinions expressed at earlier trials is proper;[34] but

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[33] See City of Garland v. Stevener, Tex.Civ.App.1970, 462 S.W. 2d 67, 69, writ ref. n. r. e.; City of Dallas v. Holcomb, Tex.Civ. App.1964, 381 S.W.2d 347, 350, writ ref. n. r. e.

[34] Horton v. Houston & T. C. Ry. Co., 1907, 46 Tex.Civ.App. 639, 103 S.W. 467, 469, writ ref.; Traders & General Ins. Co. v. Robinson, Tex.Civ.App.1949, 222 S.W.2d 266, 269, writ ref.

an inconsistency, if there is one, may be demonstrated. As we noted earlier, the purpose of such impeachment is not to demonstrate that the expert has erred, but that he is capable of error. An expert in medicine is not exempt from the use of prior testimony to prove his fallibility.

Wyeth also urges that even if permitting the impeachment was proper, counsel for Reyes failed to lay the proper foundation for the impeachment and that therefore the court erred in allowing the cross-examination to proceed. Texas courts and this Circuit have held that to impeach a witness by showing a prior inconsistent statement, "a foundation must first be laid by asking the witness whether he made the statement, giving him an opportunity to admit or deny the statement, to correct his testimony, and to explain the apparent contradiction".[35]

Yet it is Reyes's attempt to lay precisely such a foundation to which Wyeth takes exception here. Dr. Fox's attention was drawn to his testimony in Davis v. Wyeth Laboratories, Inc., 9 Cir. 1968, 399 F.2d 121, and he was given an opportunity to examine the uncertified transcript relied upon by Reyes, out of the sight of the jury and during a luncheon recess. When court reconvened, under questioning by counsel for Reyes, Dr. Fox testified that the transcript, although "somewhat inaccurate" did contain the substance of his prior testimony. He then explained at length why his former statements were in no way inconsistent with his testimony on direct examination here. Wyeth continually objected to this attempt to lay a foundation on the ground that no foundation had been laid. Overruling such objections cannot constitute reversible error.

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[35] Ray v. Gage, Tex.Civ.App.1954, 269 S.W.2d 411, 419, writ ref.; Robertson v. M/S Sanyo Maru, 5 Cir. 1967, 374 F.2d 463, 465, cert. denied, 1970, 400 U.S. 854, 91 S.Ct. 59, 27 L.Ed.2d 91; Burton v. United States, 5 Cir. 1949, 175 F.2d 960, 965, cert. denied, 338 U.S. 909, 70 S.Ct. 347, 94 L.Ed. 560.

b) The Exclusion of Dr. Nakano's Opinion

Dr. James Nakano, a virologist and the Chief of the Poliovirus Strain Characterization Laboratory in Atlanta, Georgia, was allowed to testify that, based on his analysis of Anita's stool specimens, he had concluded that the etiological agent causing her paralysis was probably a "wild strain". The trial court, however, refused to allow Dr. Nakano, who is not a physician, to advance his opinion as to "the probable cause of Anita Reyes's paralysis". Asserting that this ruling constitutes reversible error, Wyeth points out that another of its experts who is also not a practicing physician was permitted to render an opinion as to the cause of Anita's condition, as were several other experts who based their conclusions on Dr. Nakano's laboratory findings. Aside from indicating that any error in the exclusion of Dr. Nakano's testimony was probably harmless, such arguments have little force. As we concluded in another Texas diversity action:

> Generally, the admission of . . . tendered expert testimony is a matter within the sound discretion of the trial court, and the action of the trial court in admitting or excluding such evidence will be sustained unless clearly and manifestly erroneous.

Scott v. Fancher, 5 Cir. 1966, 369 F.2d 842, 844. It is at least arguable that the effect of a disease virus on a particular human being whom he had not examined was outside of the scope of Dr. Nakano's expertise. In any event, in light of all of the testimony on the issue, the exclusion of his testimony was not so "clearly and manifestly erroneous" as to constitute reversible error.

c) The Admission of Exhibit 13

Wyeth vigorously excepts to the admission into evidence of Plaintiff's Exhibit Number 13, a document purporting to detail the suspected and confirmed cases of polio which occurred in Hidalgo County during 1970, on the ground that counsel for Reyes failed to lay the proper foundation

for admission of the document under the "business records" exception to the hearsay rule.

Exhibit 13 was first referred to during the cross-examination of Mrs. Ruth McDonald, Director of Nursing for the Hidalgo County Health Department. On direct examination, Mrs. McDonald testified that the County Health Department kept statistics and records on communicable diseases and immunization of the population in Hidalgo County and there her "employer" was Dr. Copenhaver, director of the Public Health Unit in Hidalgo and Cameron Counties. On cross-examination she was shown the challenged exhibit, and testified that she had seen the report previously "when it was made up". Mrs. McDonald also identified certain writing on the exhibit as Dr. Copenhaver's handwriting. This tended to link Wyeth with the vaccine given Anita Reyes. The Exhibit was marked "Plaintiff's 13" for identification, but was not offered in evidence.

The following day, Oscar Garza, another defense witness, who is a Health Programs Specialist for the Texas State Department of Health, was confronted with Plaintiff's Exhibit 13 on cross-examination. Exhibit 13 appeared to bear a strong similarity to a list prepared by Mr. Garza, although Mr. Garza's list evidently did not show all of the same entries, and exhibited none of the handwriting previously identified as Dr. Copenhaver's. Mr. Garza demonstrated a general familiarity with the information contained in Exhibit 13, but under interrogation by counsel for Wyeth, he testified that the list was not a record prepared or retained in the regular course of business of *his* office. Exhibit 13 was then offered in evidence by Reyes's counsel, and Wyeth objected on the ground that a proper foundation had not been laid. After a colloquy which revealed that the challenged exhibit had been appended to Dr. Copenhaver's deposition in accordance with a request that he submit all relevant records, the trial court decided

that the record had been sufficiently authenticated to justify admission.

The considerable Texas authority Wyeth marshals to support its position is of little aid, for its assumption that Texas law controls our review of the trial court's decision is erroneous. While state standards may be found to *apply* to evidentiary issues in federal courts, such questions are governed by federal standards in general, and by Fed.R.Civ.P. 43(a) in particular. Bailey v. Kawasaki-Kisen, K. K., 5 Cir. 1972, 455 F.2d 392, 397. Rule 43(a) provides:

> (a) *Form and Admissibility.*
>
> In all trials the testimony of witnesses shall be taken orally in open court, unless otherwise provided by these rules. All evidence shall be admitted which is admissible under the statutes of the United States, or under the rules of evidence heretofore applied in the courts of the United States on the hearing of suits in equity, or under the rules of evidence applied in the courts of general jurisdiction of the state in which the United States court is held. In any case, the statute or rule which favors the reception of the evidence governs and the evidence shall be presented according to the most convenient method prescribed in any of the statutes or rules to which reference is herein made. The competency of a witness to testify shall be determined in like manner.

We are less sanguine than the appellants in assuming that Texas courts would not admit this exhibit as a busness record.[36] We are aware also that it is at least arguably

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[36] The Texas policy on the admission of business records is embodied in Article 3737e, Vernon's Ann. Texas Civil Statutes (Supp. 1974).

The statute is not specific as to the proof necessary to support a judicial finding that its strictures have been met but at least one decision of the Texas Supreme Court suggests that if the testimony of a "qualified witness" supports an implied finding by the trial judge that the records in dispute were made in the regular course

admissible under the Federal Business Records Act.[37] Yet neither a protracted statutory analysis nor the

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of business and were made at or reasonably near the time of the recorded act or event, the statutory strictures will have been bridged. See University Savings & Loan Assoc. v. Security Lumber Co., Tex.Sup.Ct.1967, 423 S.W.2d 287, 290.

Here, the testimony of Nurse McDonald supported the court's finding that Exhibit 13 was a business record prepared in the regular course of the business of the Hidalgo County Health Department at or near the time in question. This is particularly true, in that Exhibit 13 was appended by Dr. Copenhaver to his deposition pursuant to a request that he submit copies of all of his records relevant to Anita Reyes's case. In light of the considerable latitude Texas affords the trial judge in admitting evidence, it is by no means clear to us that a Texas appellate court would find the admission of Exhibit 13 to have been erroneous.

[37] The business records exception to the hearsay rule is also addressed by federal statute. Title 28, United States Code, Section 1732(a) in pertinent part provides:

> (a) In any court of the United States and in any court established by Act of Congress, any writing or record, whether in the form of an entry in a book or otherwise, made as a memorandum or record of any act, transaction, occurrence, or event, shall be admissible as evidence of such act, transaction, occurrence, or event, if made in regular course of any business, and if it was the regular course of such business to make such memorandum or record at the time of such act, transaction, occurrence, or event or within a reasonable time thereafter.
>
> All other circumstances of the making of such writing or record, including lack of personal knowledge by the entrant or maker, may be shown to affect its weight, but such circumstances shall not affect its admissibility.

The resemblance of this federal provision to the Texas statute is almost familial and the interpretation given it by the court reveals a certain fraternity as well.

Generally, testimony by the custodian or another qualified witness that the records offered were kept in the regular course of business and that they were prepared at or near the time in issue is a predicate to admission under § 1732(a). See, e.g., United States v. Middlebrooks, 5 Cir. 1970, 431 F.2d 299, 302, cert. denied, 1971, 400 U.S. 1009, 91 S.Ct. 569, 27 L.Ed.2d 622. Yet nowhere does the Act

precarious *Erie* ruminations characteristic of such close cases is necessary to approve the admission of Exhibit 13 here. Rather, Rule 43(a), itself, perceived through the liberal prism of our earlier decisions, furnishes the basis for Exhibit 13's admission. Plainly enough, the Rule is a standard of admission not exclusion; all doubts are to be

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require that the foundation come from the individual who kept the records or had supervision over them; all that need be established is that the record was kept in the regular course of business. Sabatino v. Curtiss National Bank, 5 Cir. 1969, 415 F.2d 632, 635, cert. denied, 1970, 396 U.S. 1057, 90 S.Ct. 750, 759, 24 L.Ed.2d 752. And, as Judge Thornberry suggests in his able analysis of Section 1732 in *Sabatino*, the determination whether a record has been kept in the regular course of business should be made in light of the purposes of the statute:

> [T]he decisions excluding offered items indicate that the main reason for the statutory language "in regular course of any business" is to provide a check on trustworthiness, in that (1) the records must be kept pursuant to some routine *procedure* designed to assure their accuracy, (2) they must be created for *motives* that would tend to assure accuracy (preparation for litigation, for example, is not such a motive), and (3) they must not themselves be mere cumulations of hearsay or uninformed opinion.

415 F.2d at 637.

Viewed in this way, the summary of suspected and confirmed polio cases in Hidalgo County submitted by Dr. Copenhaver may well have been admissible under the Act. The nature of the report itself and Nurse McDonald's testimony that she had seen the report as it was being compiled at the County Health Department indicate that it was routinely prepared. Obviously the Health Department's motive for accuracy in recording data on so serious an illness would be strong, and the data itself would reflect opinion from sources well-informed. Since the trial court here chose to admit the report once it was satisfied that the record was kept in the regular course of business, that determination can be altered only upon a showing of abuse of discretion. United States v. Middlebrooks, *supra*, 431 F.2d at 392. Were we required to rely upon the Federal Business Records Act, we do not believe that such an abuse would be found.

resolved in favor of admissibility,[38] and even evidence not perceived as admissible when viewed through the receptive trifocals of Rule 43(a), is not necessarily to be excluded.[39] This expansive standard was conceived in Monarch Insurance Co. v. Spach, 5 Cir. 1960, 281 F.2d 401, 411, and born in Dallas County v. Commercial Union Assurance Co., 5 Cir. 1961, 286 F.2d 388, 395, decisions which point the way to our approval of the admission of Exhibit 13 here.

In *Monarch Insurance*, the Court faced the difficulty of interpreting Rule 43(a)'s sanction of evidence admissible "under the rules of evidence heretofore applied in the courts of the United States on the hearing of suits in equity". On its face, this formula might be read as endorsing admission of only that evidence admissible under specific pre-1938 equity precedents. But the notion that in order to admit such evidence the court must pore over ancient volumes in search of pre-Federal Rules dogma was firmly interred, so far as this Court is concerned, by *Monarch Insurance*. Judge, now Chief Judge Brown, writing for the Court, pointed out that the district court sits as a court of equity, and the trial judge is not pinioned to pre-1938 holdings: "his chief censor is the conscience of a Chancellor." Dallas County v. Commercial Union Assurance Co., 286 F.2d at 395.[40] Moreover, not only did

[38] Bailey v. Kawasaki-Kisen, K.K., 5 Cir. 1972, 455 F.2d 392, 397; Household Goods Carriers' Bureau v. Terrell, 5 Cir. 1971, 452 F.2d 152, 160 (en banc); Butler v. Southern Pacific Co., 5 Cir. 1970, 431 F.2d 77, 79, cert. denied, 1971, 401 U.S. 975, 91 S.Ct. 1196, 28 L.Ed.2d 325.

[39] See, e.g., Price v. United States, 5 Cir. 1964, 335 F.2d 671, 677; Dallas County v. Commercial Union Assurance Co., 5 Cir. 1961, 286 F.2d 388, 394.

[40] Moreover, the fact that as an action for damages this suit would not have sounded in equity at common law does not prevent the district judge from admitting Exhibit 13 under the "suits in equity" provision, if equitable principles would have authorized its admission in an equitable action. See, e.g., Treharne v. Calla-

Monarch Insurance greatly expand the scope of evidence admissible within the strictures of Rule 43(a), it also signalled the advent of a still more liberal standard by suggesting that the Rule "does not purport to prohibit the admission of other relevant material probative evidence which, in the considered exercise of judicial wisdom, is trustworthy" 281 F.2d at 411.

The other shoe was dropped a year later in Dallas County v. Commercial Union Assurance Co., when we flatly held that a federal court is not required to cram proffered evidence into one of Rule 43(a)'s pigeonholes in order to find it admissible. Nor must the court find that the exhibit or testimony is within a "readily identifiable and happily tagged" exception to the hearsay rule to admit it. 286 F.2d at 398. Rather, in the words of *Dallas County*, if the exhibit is "necessary and trustworthy, relevant and material", the trial judge is free to exercise his discretion and admit it, so long as he keeps the hearing within reasonable bounds. 286 F.2d at 394, 398; Price v. United States, 5 Cir. 1964, 335 F.2d 671, 677.

From our review of the transcript it is plain that reception of Exhibit 13 posed no threat to the proper conduct of the trial. Neither party contests the exhibit's materiality or relevance; indeed the damage which the appellants allege resulted from its admission establishes those characteristics beyond any doubt. Since Exhibit 13 was "necessary and trustworthy", it was properly admitted under the liberal *Dallas County* standard.

Supporting this conclusion are several post-*Dallas County* decisions by this Court. In Butler v. Southern Pacific Co., 5 Cir. 1970, 431 F.2d 77, 80, cert. denied, 1970, 401 U.S. 975, 91 S.Ct. 1196, 28 L.Ed.2d 325, a proffered report was held to be necessary because information in it went "to the

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han, 3 Cir. 1970, 426 F.2d 58, 62-63; Hope v. Hearst Consolidated Publications, Inc., 2 Cir. 1961, 294 F.2d 681, 688-690, cert. denied, 1902, 368 U.S. 956, 82 S.Ct. 399, 7 L.Ed.2d 388; 9 C. Wright & A. Miller, Federal Practice and Procedure, § 2403 at 317 n. 39.

heart of the case" and it was trustworthy because it was in the "direct financial interest" of the maker of the report to prepare it accurately. In the other instance, Sabatino v. Curtiss National Bank, 5 Cir. 1969, 415 F.2d 632, 636, cert. denied, 1970, 396 U.S. 1057, 90 S.Ct. 750, 759, 24 L.Ed.2d 752, trustworthiness was revealed both by the financial interest of the keeper of the record in its accuracy, and the fact that it "was kept according to a regular procedure of entries made contemporaneously with the events it recorded". There was no question of necessity; the sponsoring witness was dead.

So analyzed, the report at issue here was properly admitted. The report of suspected and confirmed polio cases, inscribed with the word "Wyeth," was crucial in linking Wyeth to the vaccine which allegedly caused Anita Reyes's polio. Although it does not appear from the record why Dr. Copenhaver did not testify at trial, we do not believe that Reyes was required to demonstrate his unavailability in order to meet the necessity test. Cf. Butler v. Southern Pacific Co., 431 F.2d at 80. There were also sufficient indicia of trustworthiness to justify admission. Nurse McDonald testified that she had witnessed the report's preparation, and that it was laden with Dr. Copenhaver's handwriting. The motivation for accuracy in a record prepared by a public health official concerning outbreaks of serious disease within an area committed to his charge is obvious. A brand of expertise sufficient to insure accuracy may be assumed; there can be no suggestion that in analyzing poliomyelitis cases Hidalgo County Public Health officials were amateurish or careless. The notation as to the origin of the lot number of the vaccine ingested by Anita Reyes shares this reasonable presumption of accuracy. Exhibit 13, necessary and trustworthy, met this Court's strictures for admission.

(d) The Sufficiency of the Evidence

Finally, we confront the appellant's contentions that the trial court erred in denying its motions for a directed ver-

dict, for judgment notwithstanding the verdict, and for a new trial. One argument urged by Wyeth in support of this conclusion—that there was no evidence that Wyeth had a duty to warn Anita Reyes—we discussed in dealing with the substantive law. Thus here we need consider only the contentions that the evidence was insufficient to support the verdict and judgment, that the verdict was the result of passion and prejudice, and that it was against the clear weight of the evidence.

The yardstick against which such motions must be measured is a federal one:

> On motions for directed verdict and for judgment notwithstanding the verdict the Court should consider all of the evidence—not just that evidence that supports the non-mover's case—but in the light and with all reasonable inferences most favorable to the party opposed to the motion. If the facts and inferences point so strongly and overwhelmingly in favor of one party that the Court believes that reasonable men could not arrive at a contrary verdict, granting of the motions is proper. On the other hand, if there is substantial evidence opposed to the motions, that is, evidence of such quality and weight that reasonable and fair-minded men in the exercise of impartial judgment might reach different conclusions, the motions should be denied, and the case submitted to the jury.

Boeing Co. v. Shipman, 5 Cir. 1969, 411 F.2d 365, 374. As an appellate court, our sole function is to ascertain whether there is a rational basis in the record for the jury's verdict; we are forbidden to usurp the function of the jury by weighing the conflicting evidence and inferences and then reaching our own conclusion.[41]

There was conflicting testimony as to the cause of Anita Reyes's polio. In answer to a special interrogatory, the

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[41] Borel v. Fibreboard Paper Co., *supra* note 5, 493 F.2d at 1092; Helene Curtis Industries, Inc. v. Pruitt, *supra* note 12, 385 F.2d at 850.

jury found, despite the testimony of Wyeth's expert witnesses to the contrary, that Anita's polio was vaccine-induced. Essentially Wyeth complains that the jury credited the testimony of the physician who treated Anita Reyes rather than evidence offered by its parade of experts. Presented with conflicting credible evidence, such a determination was within the jury's prerogative; expert witnesses appear to assist in the court's decision-making process, not to control it. Houston Natural Gas Corp. v. Pearce, Tex.Civ.App.1958, 311 S.W.2d 899, 909, writ ref. n. r. e.; see Steakley, Expert Medical Testimony in Texas, 1 St. Mary's L.J. 161-162 (1969). The rule is the same in the Fifth Circuit. See Alman Brothers Farm & Seed Mill, Inc. v. Diamond Laboratories, Inc., 5 Cir. 1971, 437 F.2d 1295, 1298. The evidence for Wyeth was somewhat persuasive; there is no doubt about it. The evidence for Reyes was substantial and at least as persuasive, looking at the record coldly. Consequently, the trial court was guilty of no error in denying Wyeth's motions for a directed verdict and judgment n. o. v. Denial of a motion for a new trial will be reversed only upon showing of clear abuse of discretion by the trial court, Davis v. Yellow Cab Co., 5 Cir. 1955, 220 F.2d 790, 791. In light of the conflicting evidence, the denial of the motion reveals no abuse here.

IV.

Finally, we come to a series of contentions under the general heading of challenges to comments, instructions, and charges by the trial judge. Some of these have already been considered. Remaining are Wyeth's objections to specific instructions by the trial court, particularly: (1) its definition of the term "epidemic," (2) its failure to define "medically cognizable risk," and (3) its failure to instruct the jury as to the issue of "relative risk".

Federal courts apply their own rules[42] in the manner and method of charging the jury. Where state rights are involved, state law must, of course, be looked to for the substance of the instructions, but the form of the charges and the language employed to convey the substance are procedural, hence federal, concerns. See 9 C. Wright & A. Miller, Federal Practice and Procedure, § 2255 at 651 (1971). Where as here, the issues are submitted upon a general verdict to be accompanied by answers to specific interrogatories, the Federal Rules provide simply that, "[t]he court shall give such explanation or instruction as may be necessary to enable the jury to make answers to the interrogations and to render a general verdict. . . ."[43] Not surprisingly, then, while a litigant is entitled to have the trial judge advise the jury of his theories and claims (to the extent they are supported by the evidence adduced at trial), the actual form of the instructions is within the trial court's discretion. Counsel cannot, therefore, require that an instruction be rendered in the categorical language that he fancies would be most beneficial to his cause.[44]

To requests for use of specific verbal formulae, definitions, or synonyms a rule of reason should apply. Unadorned language comprehensible to the average juror, not legal jargon, should characterize the instructions. Words familiar to persons of average intelligence do not require definition.[45] In reviewing the linguistic choices

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[42] Barrett v. Virginian Ry. Co., 1919, 250 U.S. 473, 39 S.Ct. 540, 63 L.Ed. 1092; Nudd v. Burrows, 1875, 91 U.S. 426, 23 L.Ed. 286.

[43] See note 27 *supra*.

[44] Delancey v. Motichek Towing Service, Inc., 5 Cir. 1970, 427 F.2d 897, 902; Kayo Oil Co. v. Sammons, 5 Cir. 1963, 321 F.2d 729, 730.

[45] See McClendon v. Reynolds Electrical & Engineering, 5 Cir. 1970, 432 F.2d 320, 323; Government Employees' Insurance Co. v. Davis, 5 Cir. 1959, 266 F.2d 760, 765; 9 C. Wright & A. Miller, *supra*, § 2556 at 657-58.

made by the trial court, the charge must be read as a whole. An ambiguous phrase or inaccurate clause does not necessarily destroy an entire instruction. Delancey v. Motichek Towing Service, Inc., 5 Cir. 1970, 427 F.2d 897, 901. Rather, the test is whether the charge, viewed as a whole, was sufficiently clear and accurate to be understood by jurors of ordinary intelligence, and to be applied by them to the evidence so as to reach a proper conclusion. [46]

Wyeth's objections to the instructions here do not present serious difficulties. The appellant first contends that the issue whether there was a polio epidemic in the Rio Grande Valley at the time Anita Reyes contracted the disease should never have been presented to the jury, and, alternatively, that the trial judge's definition of the term "epidemic" was erroneous. It is manifest that both arguments center on the definitional dispute. Wyeth produced eight expert medical and epidemiological witnesses, each of whom testified that in his opinion a polio epidemic existed in Hidalgo County, Texas in May 1970. To arrive at this conclusion, Wyeth's experts employed an "epidemiological definition" of epidemic, according to which two cases within a given city, county, or metropolitan area in a four week period may constitute a polio epidemic. [47] Dr. Ramiro R. Casso, the Hidalgo County general practitioner who testified as Reyes's medical expert, referred to a medical dictionary to define "epidemic" as "[disease] attacking many

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[46] Rivers v. Angf. A/B Tirfing, 5 Cir. 1971, 450 F.2d 12, 15; McGuire v. Davis, 5 Cir. 1971, 437 F.2d 570, 574.

[47] This definition, which appeared as part of the 1969 Recommendations of the United States Public Health Service's Advisory Committee on Immunization Practice, is as follows: "An 'epidemic' of poliomyelitis is defined as two or more cases caused by the same polio virus type and occurring within a four-week period in a circumscribed population such as that of a city, county or metropolitan area."

people in any region at the same time".[48] From a review of its comments during the trial it is apparent that the court, properly, did not consider itself bound by either definition,[49] although in its instructions to the jury the court employed a definition not unlike that read from the medical dictionary by Dr. Casso.[50]

Here the question whether there was an epidemic in Hidalgo County during the relevant period bore directly on an ultimate issue of fact. Did Anita Reyes contract polio from a wild virus strain or from the defendant's vac-

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[48] This definition was the first, of three, appearing in Dorlan's Illustrated Medical Dictionary, Twenty-Fourth Edition, which Dr. Casso testified was "the most generally accepted dictionary by medical people."

[49] For example, at the precharge deliberations, the court observed:

> You see, I don't think we are bound by what these doctors say, or the government says, or what anybody says about the fact what an epidemic is.

But see footnote 50.

[50] The court instructed:

> Now we are talking about epidemic and we have heard lots of testimony here about two cases within thirty days or four cases within thirty days, and all these doctors have testified to that. Some of them say for operational purposes. Well, that's the evidence you can take into consideration on whether or not there was any epidemic in the area. But for our purpose here I am going to tell you that under the law that the term epidemic is a relative term, and the question of how many cases constitute an epidemic is a question of fact depending upon the prevailing circumstances. The term epidemic in its common and ordinary meaning applies to any disease which is widely spread or generally prevailing at a given place and time. That is what an epidemic is. You will be guided by that definition.
>
> Now if you find that there was an epidemic and that this girl got her paralytic polio from the wild virus as the defendant would let us view the evidence, because of the report of Dr. Nakano that there is probably a wild virus, then you have to say by your verdict she did not contract the paralytic polio as a result of having taken the defendant's vaccine.

cine? In light of its importance, the trial judge submitted the "epidemic" issue to the jurors; they had heard the conflicting testimony. He defined "epidemic" in terms pertinent to determining the question of causation. He declined to use Wyeth's "epidemiological definition", a definition that might have confused the jurors. He did not abuse his discretion in doing so. The substance of the charge was correct, and the appellants were not entitled to an instruction in the specific terms they desired.

Wyeth objected to the trial court's failure to define the term "medically cognizable risk" used in Interrogatories Nos. 3 and 4 and its failure to charge the jury on the issue of "relative risk". Wyeth insists that a definition of "medically cognizable risk" was necessary to insure that the jury would realize that there had to exist some danger or risk from the vaccine in order to conclude that Wyeth had a duty to warn.

Yet whatever the form of the interrogatories, the link between "medically cognizable risk" and "duty to warn" was made clear by the court's instructions.[51] It appears

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[51] In explaining the interrogatories to the jury the court instructed:

> Now if you find that she did get the polio from this vaccine and not from a wild virus, then I must ask you do you find from a preponderance of the evidence that on May 8, 1970, there was a medically cognizable risk that Anita Reyes might contract paralytic polio by taking trivalent oral vaccine. We have to view this as of May 8th, at that time. Did Wyeth know that this trivalent oral vaccine that they were selling to the State of Texas to immunize children was unavoidably dangerous—I mean unreasonably dangerous or unavoidably unsafe, and should they have advised the parents of Anita of this risk? Did they know that their product was unreasonably dangerous or unavoidably unsafe to be given in the southern tier of states between the months of April and November or March and November, I mean? Did they know that? And if they knew it or should have known it, did they give them warning, to the consumer? And in that connection I tell you that the law is that if you find that the product was unreasonably

to us that the challenged interrogatories were neither confusing nor misleading:

"INTERROGATORY NO. 3

"Do you find from a preponderance of the evidence that on May 8, 1970, there was a medically cognizable risk that Anita Reyes might contract paralytic polio by taking trivalent oral vaccine?

"The jury will answer 'there was a risk' or 'there was not a risk'."

"INTERROGATORY NO. 4

"Do you find from a preponderance of the evidence that there was a medically cognizable risk that Anita Reyes might contract paralytic polio by taking the vaccine after March 31st, and before November 1, 1970?

"The jury will answer 'there was a risk' or 'there was not a risk'."

The terms [sic] "medically cognizable risk" is self-defining, clear, and comprehensive to men of average intelligence; it need not be belabored in jury instructions. Use of these interrogatories did not prejudice Wyeth's presentation of its case.

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dangerous or unavoidably unsafe, and that such condition was known to the defendant, or in the exercise of reasonable care should have been known to the defendant, the law imposes upon them a duty to use reasonable methods to inform the consumer of the nature of the product so that the consumer may evaluate whether or not he should use the product and take the risk.

The court later added:

Now they say, the way I understand it from their evidence here, that these people have failed to prove that this product was unreasonably dangerous or unavoidably unsafe, that the records show that the vaccine has worked in thousands and thousands of cases. On May 8th they didn't think there was any risk of any kind, then they had no duty—or could not find out if there was a risk—then they had no duty to warn because if I don't know of a risk how can I warn anybody? I have to know of a risk in order to have a duty to warn. So I either know about it or I should have known about it.

Wyeth contends that the trial court should have instructed the jury to consider the "relative risk" of contracting polio from the vaccine as opposed to contraction from a natural source. This, Wyeth argues, would have presented the question more fairly than did the charge on "medically cognizable risk", for the jury would have weighed the probabilities that Anita Reyes was paralyzed by vaccine-induced rather than "wild" polio virus. Yet this is precisely the consideration invited by Interrogatories 3 and 4. The distinction, therefore, is verbalistic rather than substantial and to have refused to charge in the words Wyeth preferred constitutes no error.

In two lengthy sections of its brief, Wyeth attacks the trial court's summary of the evidence in the course of instructing the jury and cites as prejudicial various comments advanced by the court during the trial. More specifically, Wyeth excepts to the court's comments on the evidence in explaining the first two interrogatories to the jury,[52] and the court's discussion of the preponderance of

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[52] Compare interrogatories 1 and 2. In his summary of evidence relevant to the first interrogatory, the trial judge made reference to the testimony of Dr. Louis Miller, a physician in the employ of the United States Public Health Service whose testimony tended to demonstrate that it was only Wyeth's vaccine that was available at the Mission clinic on May 8, 1970, the day Anita Reyes received her vaccine. Wyeth urges that since specific reference was not made to the testimony of three witnesses whose recollections cast doubt on Dr. Miller's conclusion, it was prejudiced by this summary. Aside from our conclusion in the text that the trial court fairly summarized the evidence and specifically left the factual decisions for the jury, it might be observed that the testimony Wyeth relies upon does not appear to be probative of a conclusion contrary to that reached by Dr. Miller.

Nor is the appellant's objection to the court's summary of evidence relevant to the second interrogatory meritorious. Essentially, Wyeth seeks to reargue the court's failure to employ its epidemiological definition of "epidemic" in the charge and summary. We have discussed that contention earlier in the opinion.

the evidence standard.[53] Wyeth asserts that in each instance the court's summary of the evidence unfairly emphasized Reyes's theory of the case at the expense of its own. We disagree with Wyeth's assertion. Federal trial courts have a proper discretion in summarizing and commenting upon the evidence in an effort to expedite the jury's determination of factual issues. See, e. g., Trezza v. Dame, 5 Cir. 1967, 370 F.2d 1006, 1008-1009. Indeed, explanatory comments are prejudicial only when the court fails to make clear to the jurors that they alone have the burden of decision. See Stuckey v. Andrews, 5 Cir. 1957, 249 F.2d 828; 11 C. Wright & A. Miller, supra, § 2886 at 292-294 and n. 73. Here the trial court went to great lengths to impress upon the jurors that they were the exclusive arbiters of

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[53] The "preponderance of the evidence" instruction rendered by the court was scarcely novel, yet Wyeth contends that it was prejudiced by the court's admonition that the jury ought not be influenced by the number of witnesses produced by either party. The court instructed:

> Preponderance of the evidence also means that it is the evidence that you believe believable. Doesn't depend on numbers of witnesses because ten people can sit up here and tell you that the horse he saw was black, and one man can come up here and testify that the horse he saw was white. And if you believe the man that says it was white then you can disregard the ten that said it was black, see, if the reasons he gives for telling you the horse is white seem more plausible to you, see, or preponderates. So the number of witnesses has nothing to do with this. It is the quality of the evidence and the reasons for the evidence that count. So that is another way of telling you what preponderance of the evidence means.

This segment of the court's charge was error, Wyeth asserts, in that it abraded the impact of Wyeth's extensive expert testimony. To the contrary, we find that offered in the midst of a lengthy and accurate charge explaining preponderance, such an explanation is laudable to the extent that it tends to concentrate the vision of the jury on the preponderance of *believable* evidence rather than the numerical superiority of witnesses or exhibits. It certainly was not error.

the facts, the sole judges of the witnesses' credibility.[54] Since we also conclude that the summaries and comments upon the evidence were basically fair, we find no ground for reversal here.

Finally, Wyeth contends, in an argument bolstered by twenty-three detailed references to the trial transcript, that the cumulative effect of the trial court's comments on the evidence and sympathetic references to Anita Reyes so prejudiced its case as to require reversal. We shall not attempt to consider the challenged comments separately. We have examined the transcript from beginning to end. We have paid particular attention to the court's instruction to the jury. We hold that the court's comments were generally designed to fulfill its responsibility to keep the trial progressing on course and at a proper pace. A trial judge takes no vow of silence; he vows to follows the law, to be fair, and to serve as an arbiter in the interests of justice. See Nordmann v. National Hotel Co., 5 Cir. 1970, 425 F.2d 1103, 1109. We consider that the trial judge conducted a fair trial. Nevertheless, we do not approve of the trial judge's over-frequent references to Anita Reyes as "this little girl". It was obvious to all that Anita was a little girl. And she was the victim of a great tragedy. But judges must steel themselves to avoid any comment that a jury might construe as bias in favor of any "little girl", or

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[54] The court admonished at the outset of its charge:

> Now you are the exclusive judges of the facts and the credibility of the witnesses and the weight to be given to their testimony. But the law you must take from me for it would be a violation of your sworn duty as jurors to take any other view of the law other than that as I give it to you.
>
> Now during the trial of this case it has been necessary for me to make rulings on objections. I have also asked some witnesses questions, and during the conduct of this trial if you have gotten any ideas that I am leaning one way or another in this case I want you to dispel that from your mind because that was not my intention. I am very happy to have you decide the facts in the case and relieve me of that responsibility.

any injured claimant. Here, a thorough examination of the transcript, consideration of the trial judge's rectitude throughout the trial, and the trial judge's curative instruction [55] to the jury convince us that his references to Anita as "this little girl" were not so harmful to Wyeth's cause as to constitute reversible error.

V.

In closing, we feel that we should comment on the important policy considerations raised in the briefs of the amici curiae, the American Academy of Pediatrics [AAP] and the Conference of State and Territorial Epidemiologists [CSTE]. Both insist that the holding we reached is "dangerous" to the nation's preventive medicine programs and contravenes a strong public policy favoring large-scale participation in immunization efforts to combat infectious disease. The crucial points of the argument are two: first, that any effort to warn vaccinees will be futile and frightening, leading only to confusion, and second, that a warning is unnecessary once epidemiologists have reached a deliberate medical judgment that universal vaccination is necessary. These public health policy questions cut across the law. We realize their importance.

Citing a recent Texas statute which requires that all Texas schoolchildren receive polio vaccine, [56] the AAP insists that this renders any warnings futile. This argument assumes, of course, that the only options available are to ingest the oral vaccine at the clinic or to eschew immunity. Obviously, however, one can choose to be innoculated with killed-virus Salk vaccine, either to provide complete immunity or as a precautionary prelude to ingesting oral vaccine. The AAP also insists that the warnings would be so complex or misleading as to confuse and frighten potential vaccinees. This is possible. Yet we believe that a warning

[55] See note 54, *supra*.

[56] 67 Tex.Stat.Rev. § 209(a) (1971).

advising a patron of a public health clinic of the relative risk of contracting polio from a "wild" source against the slight chance of contracting it from the vaccine would not be terrifying or confusing. Some would be sufficiently concerned to take the Salk vaccine innoculation. Others, perhaps those who, like the plaintiff in *Davis*, have as great a chance of contracting polio from the vaccine as contracting it from a wild source, will undoubtedly be deterred from immunization. The AAP's answer to this problem is to warn no one. That is no answer.

This position raises a policy consideration scarcely less urgent than the need for mass immunization from disease; the right of the individual to choose and control what risk he will take, in the absence of an individualized medical judgment by a physician familiar with his needs and susceptibilities. Recognition of this right counters the argument advanced in the CSTE's brief that once an epidemiological balancing of the risks of immunization has been made, no warning is required. Clearly, the rationale excusing warnings to ultimate consumers of prescription drugs whose physicians have balanced the risk for them, cannot be extended to a medical determination that statistical probabilities justify universal immunization. In such cases, the test is that outlined in *Davis:*

> When . . . the risk qualitatively (e. g., death or major disability) as well as quantitatively, on balance with the end sought to be achieved, is such as to call for a true choice judgment, medical or personal, the warning must be given.

399 F.2d at 129-130. Here the qualitative risk was great, the quantitative risk minute. The end sought to be achieved —immunization—is important both to the individual and society. Striking the balance in this case is difficult, but by adding two elements to the *Davis* calculus we conclude that a sufficient "true choice judgment" was involved here to lend strong policy support to our holding. First, the risk

here was foreseeable statistically, although unknowable individually. Thus, unlike the abreaction cases, here there was a basis for rational choice. Second, a choice here, if given, had an opportunity to be efficacious, since reasonable alternatives to taking the oral vaccine were available. Therefore, the choice was not so clear cut that even offering the opportunity to choose was meaningless.

Moreover, there is a third policy factor at work here overlooked by the amici:

> Until Americans have a comprehensive scheme of social insurance, courts must resolve by a balancing process the head-on collison between the need for adequate recovery and viable enterprises. . . . This balancing task should be approached with a realization that the basic consideration involves a determination of the most just *allocation of the risk of loss* between the members of the marketing chain.

Helene Curtis Industries, Inc. v. Pruitt, *supra*, 385 F.2d at 862. Statistically predictable as are these rare cases of vaccine-induced polio, a strong argument can be advanced that the loss ought not lie where it falls (on the victim), but should be borne by the manufacturer as a foreseeable cost of doing business, and passed on to the public in the form of price increases to his customers.[57]

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[57] See, e. g., Calabresi & Bass, Right Approach, Wrong Implications: A Critique of McKean on Products Liability, 38 U.Chi.L. Rev. 74 (1970); Calabresi, Some Thoughts on Risk Distribution and the Law of Torts, 70 Yale L.J. 499 (1961); Morris Enterprise Liability and the Actuarial Process—The Insignificance of Foresight, 70 Yale L.J. 554 (1961); 46 N.Y.U.L.Rev. 403 (1971); see also Escola v. Coca Cola Bottling Co., Cal.Sup.1944, 24 Cal.2d 453, 150 P.2d 436, 440 (Traynor, J., concurring). It can also be argued, of course, that since all society benefits from universal immunization against infectious disease, the loss should be borne by the local, state or federal government. Unless the doctrine of sovereign immunity is significantly altered, however, such a loss distribution scheme does not appear to be likely. See Merrill, Compensation for Prescription Drug Injuries, 59 Va.L.Rev. 1, 102 (1973).

Contrary to the assertions of the AAP and the CSTE, we feel strongly that our holding is in accord with public policy considerations. We recognize both the essential role the city health clinic and the rural county clinic play in the nation's public health scheme, and the dangers that their depersonalized medical treatment pose.[58] We do not then, lay down an absolute duty to warn all who receive medication at public clinics. Instead, we hold that in the case of a prescription drug which is unavoidably unsafe, and as to which there is a certain, though small, risk throughout the population, there must be *either* a warning—meaningful and complete so as to be understood by the recipient—*or* an individualized medical judgment that this treatment or medication is necessary and desirable for this patient. Anita's parents received neither. Wyeth is therefore liable for the consequence of its failure to market its unavoidably unsafe product in such a way as to warn Anita's parents of its unreasonably dangerous condition.

The judgment is affirmed.

APPENDIX A: INTERROGATORIES

The interrogatories submitted to the jury and the jury's answers are as follows:

INTERROGATORY NO. 1

Do you find from a preponderance of the evidence that Anita Reyes received a polio vaccine from Defendant Wyeth's Lot No. 15509?

The Jury will answer "She did" or "She did not".

We, the Jury, answer: She did.

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[58] See 56 Geo.L.J. 1016 (1968); 5 San Diego L.Rev. 422 (1968).

INTERROGATORY NO. 2

Do you find from a preponderance of the evidence that Anita Reyes contracted paralytic polio as a result of having taken Defendant's vaccine?

The Jury will answer "She did" or "She did not".

We, the Jury, answer: She did.

If you answered this "She did not", then you need not answer any other issue.

INTERROGATORY NO. 3

Do you find from a preponderance of the evidence that on May 8, 1970, there was a medically cognizable risk that Anita Reyes might contract paralytic polio by taking Trivalent Oral Vaccine?

The Jury will answer "There was a risk" or "There was not a risk".

We, the Jury, answer: There was a risk.

INTERROGATORY NO. 4

Do you find from a preponderance of the evidence that there was a medically cognizable risk that Anita Reyes might contract paralytic polio by taking the vaccine after March 31st, and before November 1, 1970?

The Jury will answer "There was a risk" or "There was not a risk".

We, the Jury, answer: There was a risk.

If you have answered either or both interrogatories No. 3 and 4 "There was a risk", then you will answer the following Interrogatory.

INTERROGATORY NO. 5

Do you find from a preponderance of the evidence that the Defendant Wyeth failed to warn the parents of Anita Reyes of the risk that you have found so that they could make their choice?

The Jury will answer "They failed" or "They did not fail".

We, the Jury, answer; They failed.

INTERROGATORY NO. 6

What sum of money, if paid now in cash, would compensate Anita Reyes for the injuries sustained by her?

The Jury will answer in dollars and cents.

We, the Jury, answer: $200,000.00.

APPENDIX B: POLIOMYELITIS

It was not until about 1950 that scientists and physicians really began to understand how poliomyelitis attacks its victims. They learned that polio is caused by an enterovirus which grows in the intestinal tract, but that the virus is introduced into the body orally, through the mouth. After entering the body, the virus reproduces rapidly in the alimentary tract, and when it reaches the lower intestinal tract its growth causes what could be termed an "infection". This does not mean that the individual "infected" has contracted polio; upwards of 80 percent of the population is naturally immune to polio virus, and only about one of every hundred persons who experience the intestinal viral infection will later manifest clinical symptoms of polio. When disease does result, medical scientists believe, the virus moves, perhaps through the bloodstream, from the intestinal tract or alimentary tract to the spinal column, where it attacks the anterior horn cells, the "grey matter"

within the spinal column. Destruction of sufficient "grey matter" will result in "motor neuron disease", that is, muscular paralysis.

The initial problem facing researchers attempting to develop a vaccine—cultivation of a growth of polio virus in tissue outside the body—was solved by Dr. Enders at Harvard University in 1949. The scientists also learned that polio virus was of three distinct types, and that to provide effective protection, a vaccine would have to immunize the vaccinee to all three types.[59] The first breakthrough resulted from the research of Dr. Jonas Salk, who perfected a "killed virus" vaccine to be administered by innoculation. To produce this vaccine, polio virus is grown in a tissue culture and clinically "killed", that is, rendered incapable of causing disease. In killing the virus, however, no chemical alteration occurs and when it is introduced into the body in the vaccine, the virus acts as an antigen to prompt the production of antibodies. Should a wild or virulent strain of polio virus enter the bloodstream, the antibodies generated as a reaction to the vaccine will destroy it, and the vaccinee will avoid polio.

In 1955 after extensive tests were conducted under the auspices of The National Foundation for Infantile Paralysis (March of Dimes) the researchers concluded that the Salk vaccine was effective and, if the virus were killed, completely safe.[60] The Salk vaccine then became the primary

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[59] These are commonly referred to as Type I, Type II and Type III, respectively. To the extent that the differences among the three types are relevant, they are referred to in the text. It is undisputed, however, that Anita Reyes suffers from Type I polio.

[60] When Salk vaccine which inadvertently contained some unkilled virulent viral strains was released for use, however, as in the "Cutter incident" of 1955, several cases of vaccine-induced polioymelitis resulted. See, Gottsdanker v. Cutter Laboratories, Cal.App.1960, 182 Cal.App.2d 602, 6 Cal.Rptr. 320.

weapon against polio. But the killed virus vaccine nonetheless exhibited several drawbacks. It had to be injected by hypodermic needle, and a separate innoculation was required for each type of polio virus, as were repeated "booster" injections. Most importantly, perhaps, the Salk vaccine failed to immunize the intestinal tract of the vaccinee. Thus, individuals themselves immunized could still pass the virus to non-immune persons with whom they came in contact. These limitations led to efforts to produce a completely effective oral vaccine, the most successful of which was that of Dr. Albert Sabin. Developed in the middle and late 1950's, the Sabin oral vaccine introduced living but attenuated polio virus into the recipient's system. An attenuated polio virus is one which laboratory processes have rendered incapable of producing disease (to the extent of attenuation), but which retains sufficient strength to cause the production of antibodies to resist and destroy an attacking wild or virulent polio virus in the vaccinee's alimentary tract. Three types of "monovalent" vaccines were developed, one to deal with each type of polio virus, but through a "titering" or mixing process, a single "trivalent" oral vaccine can be produced which, upon ingestion, will provide protection against all three types of virus.

Like its "killed virus" predecessor, the Sabin vaccine was extensively tested worldwide to determine whether it was safe and effective for general use. When favorable results were achieved, the vaccine was licensed for manufacture and sale in the United States by the Division of Biologic Standards of the National Institute of Health [D.B.S.], an arm of the Department of Health, Education and Welfare. Wyeth Laboratories was among the three original licensees who were authorized to prepare and distribute the vaccine only as a prescription drug. Irrespective of which licensee prepares the vaccine, it is derived from a common source: a seed virus obtained from Dr. Sabin. The "seed virus" from which Wyeth Laboratories

vaccine is produced was obtained from Dr. Sabin by Pfizer, Ltd., of England, and is repeatedly reproduced by them in a culture of monkey tissue. Reproduction is rapid, and the virus is frequently "harvested" and the vaccine prepared in separate "lots". At this point Pfizer conducts extensive tests on each lot to ensure that it is safe and effective. Once satisfied by its laboratory findings, Pfizer ships the lot of vaccine to the D.B.S., where it is again subjected to rigorous testing.[61] If the vaccine meets D.B.S. standards, it is released to the manufacturing laboratory, where the vaccine is titered or mixed.

Despite careful preparation and testing, it is apparent that live virus oral polio vaccine cannot be stripped of all danger. As early as January 1961, a subcommittee of a Health, Education and Welfare Department Committee on Poliomyelitis Control expressed concern about the "known potentiality of reversion to virulence of live poliovirus vaccine." A year and one-half later, both a subcommittee of the Association of State and Territorial Health Officers and the Surgeon General's own Special Advisory Committee on Oral Poliomyelitis Vaccine, concluded that, at least where Type III oral vaccine was concerned, a causal connection exists between administration of the vaccine and the occurrence of poliomyelitis in some adults. Thus a "small but definite risk" attaches in feeding Type III oral vaccine to adults.[62] By July 1964, with more data available, the Surgeon General's Special Committee found that 15 cases of polio deemed *compatible* with vaccine causation had followed ingestion of Type I vaccine, 2 had followed ingestion of Type II, and 36 had followed ingestion of Type III. The Committee concluded that "at least some

[61] A more extensive discussion of the nature and complexity of the tests may be found in Griffin v. United States, E.D.Pa.1972, 351 F.Supp. 10.

[62] See Davis v. Wyeth Laboratories, 9 Cir. 1969, 399 F.2d 121, 123-125.

of these cases were caused by the vaccine".[63] This is not to say that the Special Committee concluded that these cases *were* produced by the vaccine; to the contrary, the members cautioned that "no laboratory tests available can provide a definitive answer". Rather, they employed a brief catalogue of symptoms[64] which they believed would separate those cases compatible with vaccine-causation from those clearly caused by wild strains, and would further separate the "probable" vaccine-related cases from those merely possibly associated with it.[65]

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[63] Report of the Special Advisory Committee on Oral Poliomyelitis Vaccine to the Surgeon General, Public Health Service, 1964 at 4. A report by the Health, Education and Welfare Department's Center for Disease Control indicates that for the year 1964, 20 of 56 reported cases could be associated with vaccine ingestion. Center for Disease Control, [Department of Health, Education and Welfare], 1964 Surveillance Report, at 3.

[64] As paraphrased in Reyes' brief, these symptoms include:

1. An onset of illness between 4 and 30 days following feeding of the specific vaccine type in question and with[sic] an onset of paralysis not sooner than six days after the feeding.
2. Significant residual lower-motor-neuron paralysis.
3. Laboratory data not inconsistent with respect to multiplication of the vaccine virus fed.
4. No evidence of upper motor neuron disease, definite sensory loss, or progression or recurrence of paralytic illness one month or more after onset.

These compatible cases were further subdivided into "probable" and "possible" cases employing the following guidelines for "probable" cases:

1. Evidence of fever at onset of paralysis.
2. History of systemic illness preceding the development of paralysis.
3. Clinical evidence of meningeal involvement manifested either by nuchal rigidity or cerebrospinal fluid cell count greater than 10 cells per cubic milliliter.

[65] For a further discussion of the development of polio vaccine, and the elaborate testing procedures, see, e.g., Davis v. Wyeth Laboratories, Inc., 9 Cir. 1969, 399 F.2d 121; Griffin v. United States, E.D.Pa.1972, 351 F.Supp. 10; Stahlheber v. American Cyanamid Co., Mo.Sup.Ct.1970, 451 S.W.2d 48.

APPENDIX B

VERNON'S EDUCATION CODE OF TEXAS

§ 2.09. Immunization

(a) No person may be admitted to any elementary or secondary school or institution of higher education unless he has been immunized against diphtheria, rubeola, rubella, tetanus, poliomyelitis, and smallpox, except as provided in Subsection (c).

(b) Subject to the provisions of Subsection (c) the State Board of Health may modify or delete any of the immunizations in Subsection (a) or may require immunizations against additional diseases as a requirement for admission to any elementary or secondary school or institution of higher education.

(c) No form of immunization is required for a person's admission to any elementary or secondary school or institution of higher education when the person applying for admission submits to the admitting official either of the following:

(1) an affidavit signed by a doctor who is duly registered and licensed under the Medical Practice Act of Texas, in which it is stated that, in the doctor's opinion, the immunization required would be injurious to the health and well-being of the applicant or any member of his family or household; or

(2) an affidavit signed by the applicant or, if a minor, by his parent or guardian stating that the immunization conflicts with the tenets and practice of a recognized church or religious denomination of which the applicant is an adherent or member; provided, however, that this exemption does not apply in times of emergency or epidemic declared by the Commissioner of Health.

(d) The State Department of Health shall provide the required immunizations to children in areas where no local provision exists to provide these services.

(e) A person may be provisionally admitted to an elementary or secondary school or institution of higher education if he has begun the required immunizations and if he continues to receive the necessary immunizations as rapidly as is medically feasible. The State Department of Health shall promulgate rules and regulations relating to the provisional admission of persons to an elementary or secondary school or institution of higher education.

Amended by Acts 1971, 62nd Leg., p. 702, ch. 67, § 1, eff. April 26, 1971; Subsec. (b) amended by Acts 1971, 62nd Leg., p. 1443, ch. 398, § 1, eff. May 26, 1971; Subsec. (e) added by Acts 1971, 62nd Leg., p. 1441, ch. 393, § 2, eff. May 26, 1971.

APPENDIX C

PRESIDENTIAL DOCUMENTS

Title 3—The President

PROCLAMATION 4329

Immunization Action Week, 1974

By the President of the United States of America

A Proclamation

This Nation has always been committed to fostering the health of its people, and particularly of its children. Immunization against disease has been an exciting chapter in that effort. The United States can take pride in the dedicated research which has produced safe and effective vaccines against polio, measles, rubella, and other childhood diseases.

Cooperation by the medical profession and public health organizations in distributing these vaccines to children has achieved dramatic reductions in diseases which can kill, cripple, or cause birth defects, including mental retardation. Because of their tragic consequences, we dare not let down our guard against a resurgence of these diseases.

The President's Committee on Mental Retardation has brought to my attention an alarming decline of immunity levels among pre-school children. Last year more than 40 percent of these children were unprotected against either polio, measles, rubella, diphtheria, pertussis, or tetanus. On polio, for example, the Department of Health, Education, and Welfare Center for Disease Control reports that immunization levels dropped from 79 percent in 1963 to 60 percent in 1973.

Our children are America's future. Let us make that future a healthy one, for their sake and the Nation's sake.

NOW, THEREFORE, I, GERALD R. FORD, President of the United States of America, do hereby proclaim the week beginning October 20, 1974, as "Immunization Action Week," and call upon all parents, educators, and medical personnel to exert renewed efforts during this week and throughout the year to immunize every American child against diseases for which vaccines are available.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-first day of October, in the year of our Lord nineteen hundred seventy-four, and of the Independence of the United States of America the one hundred ninety-ninth.

/s/ GERALD R. FORD

[FR Doc.74—24889 Filed 10-21-74;3:56 pm]

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1974

NO. – 74-501

WYETH LABORATORIES, a division of American Home Products Corporation, a Delaware corporation,
Petitioner,

V.

EPIFANIO REYES, individually and as next friend of Anita Reyes, a minor,
Respondent.

RESPONDENT'S ANSWER TO PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH DISTRICT

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November 25, 1974

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The respondent prays that the petition for writ of certiorari to review the opinion and judgment of the United State Court of Appeals for the Fifth Circuit rendered in these proceedings, on July 31, 1974, BE DENIED.

JURISDICTION

The Petitioner predicates its Petition for a Writ of Certiorari upon two points, neither of which has heretofore been raised before the Federal District Court or the Fifth Circuit Court of Appeals.

Rule 23(1) (c) states that the Supreme Court limits the Petitioner to the points raised in the petition, and these points must properly arise in the record (Tyrrell vs. District of Columbia, 243 U.S. 1), and must have been urged and briefed below, (California vs. Taylor, 353 U.S. 553; Lawn vs. United States, 355 U.S. 339 and Neely vs. Eby Construction Co., 386 U.S. 317)

QUESTIONS PRESENTED

1. Whether by enactment of the Federal Food, Drug and Cosmetic Act, as amended, and the Public Health Service Act, as amended, Congress has so pre-empted the field applicable to the labeling of prescription biological drug products that it was error for the courts below to dispose of the case solely on the basis of local tort law.

2. Whether the Court of Appeals contravened the public health policy of the State of Texas and of the United States and erred in its application of Texas law in holding, in the face of statutorily expressed public policy of Texas to the contrary and in disregard of the holding in the only Texas case in point, that under Texas law, a manufacturer of a prescription drug, used to immunize large segments of the population against paralytic polio is required to warn the ultimate consumer of the dangers of the vaccine even though admittedly adequate warnings have been given to the physician-administrators of the public health facility dispensing the drug.

STATEMENT OF FACTS

On May 8, 1970, in Mission, Texas, which is located in the most southern part of the State in an area referred to as the Rio Grande Valley, eight-month-old Anita Reyes was taken by her mother--a woman with a seventh-grade education--for her immunizations at a public health clinic where Mrs. Reyes had taken her other twelve children.

While at the clinic this eight-month-old child received a D.P.T. shot and was fed trivalent oral polio vaccine which contained Type I, Type II, and Type III live polio virus. She was given her polio vaccine in connection with a continuing immunization program which is carried on in these clinics throughout the year. At no time was Anita's mother warned or informed of any risks involved in the taking of the vaccine in May. In fact the public health nurse who administered the vaccine, while aware of the risk, deliberately avoided advising her of any risk.

About fourteen days after receiving her polio vaccine, Anita developed a fever. On May 23 she was admitted to the Hospital with a diagnosis of paralytic polio Type I. Since then she has been permanently paralyzed from the waist down, is not able to walk, has atrophy of her left arm, and cannot control her bladder of bowel movements.

Six years before Anita was ever vaccinated, to-wit, in July, 1964, because of the continuing occurrence of cases of paralytic disease in association with the administration of the oral poliomyelitis (Sabin) vaccine, a special advisory committee had been named by the Surgeon General of the Public Health Service to make a study of the problem. After studying 123 cases the committee categorized fifty-seven as being compatible with vaccine-induced disease using the following criteria for compatible cases: (Emphasis added.)

1. An onset of illness between 4 and 30 days following feeding of the specific vaccine type in question and with an onset of paralysis not sooner than six days after the feeding.

2. Significant residual lower-motor-neuron paralysis.

3. Laboratory data not inconsistent with respect to multiplication of the vaccine virus fed.

4. No evidence of upper-motor neuron disease, definite sensory loss, or progression of recurrence of paralytic illness one month or more after onset.

These compatible cases were further subdivided into "probable" and "possible" cases employing the following guidelines for "probable" cases:

1. Evidence of fever at onset of paralysis.

2. History of systemic illness preceding the development of paralysis.

3. Clinical evidence of meningeal involvement manifested either by nuchal rigidity of cerebrospinal fluid cell count greater than 10 cells per cubic milliliter.

The record also shows that prior to the widespread use of Sabin vaccine, a Committee on Poliomyelitis Control meeting at the Center for Disease Control in Atlanta, Georgia, in January, 1961, had made reports containing the following precautions:

"Because of the unique nature of live polio-virus vaccine, with its capacity to spread the virus in a limited manner to nonvaccinated persons, the Committee cannot make

recommendations for manufacture without expressing concern about the manner in which it may be used. The seriousness of this responsibility can be illustrated, for example, by the known potentiality of reversion to virulence of live polio-virus vaccine strains, and the possible importance of this feature in the community if the vaccine is improperly used."

"5. Seasonal Limitations and Geographic Considerations

Mention has been made that in the United States the optimal time for the administration of the oral vaccine is from November 1 until May 31. For the southern tier of States, in which the poliomyelitis season as well as the season for other enterovirus infections has been recognized as starting prior to June 1, a shorter period is preferable, I. E., November 1 to March 31."

By its findings the jury concluded that Anita Reyes met all of the afore-mentioned guidelines set out by the committee for guidance of the medical profession as being a "probable" vaccine associated case, and that she was vaccinated at the wrong time of the year.

It is interesting to note that in 1964 the Center for Disease Control in its Surveillance Summary reported on Page 3 thereof that out of 56 case reports of paralytic polio for that year 20 were vaccine associated. (Page 3, 1964 Surveillance Report) (Emphasis added.) This report was available 4 years before Dr. Bierly, Wyeth's Vice-President, prepared the package insert in 1968.

The only manner in which Wyeth warned the consumers of the vaccine was by using said package insert and quoting some unrelated parts of the Surgeon General's Committee's Report. The only reference in the insert to the seasonal limitations

was as follows: "preferably should be administered during the non-polio season, if such exists in the area where the vaccine is to be used."

Dr. Ramiro R. Casso, a graduate engineer and medical doctor, the doctor who actually treated Anita Reyes, concluded that Anita Reyes met all of the criteria for both compatible and probable vaccine-caused case and that, therefore, he was of the opinion that her polio was caused by the vaccine. After studying all the statistics, he estimated that one out of every 290,000 individuals vaccinated with Sabin vaccine would contract polio from the vaccine, and further that Anita Reyes had received her vaccine during the polio season. Dr. Casso further testified that in connection with polio vaccines he had changed his system of immunizing patients because of the risks involved. He agrees that "primary emphasis should be given in all communities during their first year of life, however, in a special manner." He stated that "you have to be very much aware of the fact that the resistance that a new born has is high and it drops in the first eight to ten months of life, but they should not be immunized with live virus (Sabin) vaccine because they are less resistant." Instead of giving them oral polio vaccine (live virus), he states, "I am now giving the other one (Salk) which I know cannot cause----has no association with paralytic polio." He testified that he administers the Salk (dead virus) vaccine during their first year of life to kick up the antibodies. Then it would be safe to use the oral vaccine to give them permanent immunity. He stated further that "during their first year of life we're taking a risk by subjecting them to the oral vaccine." Regarding Sabin vaccine, he stated, "the only question that has been raised, as you know, are those of vaccine association of paralytic disease; but there has never been any question raised about the efficacy of the other vaccine, of the Salk vaccine, which was a killed virus vaccine." Local pediatricians in the County were also administering Salk vaccine (dead virus) to build up the children's antibodies prior to feeding them live virus.

Wheth offered the testimony of five doctors who had never seen Anita Reyes and had seen her hospital records only about one month prior to the trial, that is, two years after her vaccination. Each of these doctors testified that because of the opinion by Dr. Nakano that the virus was "probably wild", and the fact that seven other cases of polio had been reported from the County, Anita Reyes in their opinion had contracted polio from a wild or natural virus. Dr. Nakano admitted, however, he was only making an "educated guess". The sixth doctor presented by Wyeth was Dr. Miller, who expressed a similar opinion based on the same reasons, although he had seen Anita one time in the hospital.

It is interesting to note from the record that four of the seven cases in the Rio Grande Valley occurred after Anita's case and none had occurred in Mission, a city of 12,000, at the time.

Dr. Fox, Associate Dean, School of Public Health, and Professor of Epidemiology, University of Washington, one of the doctors who testified for Wyeth, stated that there was a risk in taking the vaccine and that the recipient should be warned of this risk. He recognized also that some of the polio cases reported had been caused by the vaccine, and that the polio season in this area was in May and June. (Emphasis added.) Dr. Dickerson, Director of Public Health for Texas, and Dr. Melneck likewise stated that in the Rio Grande Valley the polio season was May and June.

Dr. Nathanson, Professor of Epidemiology at John Hopkins and Editor of the American Journal of Epidemiology, another witness for Wyeth, who has published close to 50 papers dealing with research of virus infections of the nervous systems, also recognized that there were cases caused by the vaccine and that the risk of contracting polio from the vaccine was one case for fewer than 1 million persons vaccinated. (Emphasis added.) However, he also testified that if the two cases in the Valley (which includes Anita's case--both children

being under one year of age), in which the children had contracted polio after ingesting the vaccine were actually caused by the vaccine then the risk in this area was one out of 5,000 children. In addition Dr. Nathanson recognized the fact that it was common knowledge throughout the drug industry that the majority of the vaccine is sold to public health departments and sent to local public health clinics for use in mass administrations or community clinics where volunteers go and help give these vaccines; where no doctors are present; and where the same vial of vaccine is used to give drops of vaccine to as many as ten different babies.

DISCUSSION OF FIRST POINT

The first point submitted by Petitioner is that the Federal Food, Drug and Cosmetic Act of 1938, 52 Stat. 1040 (1938), as amended, 21 U.S.C. Sec. 301, et seq. (1970), and the Public Health Service Act, 58 Stat. 702 (1944), as amended, 42 U.S.C. Sec. 262, et seq. (1970) has so pre-empted the field of law applicable to the labeling of prescription biological drug products that it was error for the courts below to dispose of the case solely on the basis of local tort law.

Both contentions are completely without merit. In the first place, the Federal Food, Drug and Cosmetic Act is a criminal statute. U.S. vs. Lee, D. C. Wis. 1941, 40 F. Supp. 801, reversed on other grounds 131 F. 2d 464, 143 A.L.R. 1451. It was intended to protect consumers from misleading claims in connection with sale of certain products and from hazards of adulteration, mislabeling and misbranding. U.S. vs. Kuch, D.C.D.C. 1968, 288 F. Supp. 439, 35 A.L.R. 3rd 922. In enacting the Food, Drug and Cosmetic Act, the Congress had no intention to pre-empt the field relating to the retail sales of drugs and proprietary medicines in the several states. LoBlaw, Inc. vs. New York State Board of Pharmacy, 1960, 202 N.Y.S. 711.

In connection with the Federal Food, Drug and Cosmetic Act the Supreme Court has heretofore held that Congress has the right not only to pass laws which regulate legitimate commerce among the states and with foreign nations but has full power to keep the channels of such commerce free from the transportation of illicit or harmful articles, to make such as are injurious to the public health, outlaws of such commerce and bar them from the facilities and privileges thereof. McDermott vs. Wisconsin, 228 U.S. 115. This being a law designed to protect the consumer from mislabeled foods and drugs and informing purchasers as to what they were buying, it is absurd to contend that state tort law cannot be applied where the labels or package insert either fails to properly inform the ultimate consumer as to any risk associated with the use of the product or seeks to conceal the risk from the public based upon the premise that a greater number will benefit from its use than will be permanently paralyzed as a result of submitting to inoculation without knowledge of the controversial risk which is unquestionably established as being an inheritant characteristic of the drug or vaccine. Nowhere in the Act did Congress attempt to limit the tort liability of the manufacturer for injuries incurred because the product had been labeled, either properly or improperly, under the Act.

The Act itself sets out what labeling is improper. It further provides for criminal liability for improper labeling. It does not say that unless the product be shown to be improperly labeled, there can be no tort liability with respect to its use. It does not say that the sole remedy for violation of the Act is by criminal proceedings, nor does it in any way give any manufacturer or health official the right to place a vaccine in the channels of commerce which has a known risk connected with its time of use or its actual use, simply because its use would benefit more people than it would harm, without making that risk known to the person who will either benefit or suffer from its use.

Mention has been made in the Petition that it has not been and cannot be alleged that the labeling which Petitioner provided with its trivalent polio vaccine was in any way false or misleading, and that it was developed with the approval of the Federal officials. The actual testimony of Dr. Mahlon Bierly, Executive Assistant to the President of Wyeth Laboratories, in the trial of the case was that he prepared the package insert and the record is devoid of any evidence that it was approved by any federal agency. Cross-examination of Dr. Bierly revealed that the package insert was materially lacking in many respects. The only reference to the seasonal limitation was "polio virus vaccine, live, oral, preferably should be administered during the non-polio season". As to what he meant by this provision, he stated that it should be interpreted by the local physician, wherever he may practice, and he admitted that if you were to assume that the physician had only read the insert, it would not furnish him with complete information, and for a doctor to give the vaccine with safety and full knowledge of its consequences and risks involved he must go further and do further research than what is contained in the package insert.

Thus, even though the Appellant admitted in Interrogatory No. 14 that the vaccine was a prescription drug, the information on the package insert was lacking in important respects, even to a medical doctor.

DISCUSSION OF SECOND POINT

The second question presented in the Petition is whether the Court of Appeals contravened the Public Health Policy of the State of Texas in its application of the Texas law by holding, in the face of statutorily expressed public policy of Texas, to the contrary.

In this regard, reference is made to Article 2.09, Immuni-

zation, Vernon's Education Code of Texas. This statute was enacted by the 62nd Legislature of Texas in 1971, and did not go into effect until May of 1971, approximately a year after Anita contracted polio. It could have no retoractive effect and certainly was not a part of the State's public policy in May of 1970. Even had it been the law, there is nothing in the statute which requires the child to be immunized by Sabin vaccine. She would have the choice under the law to follow the procedure utilized by Dr. Casso, wherein he first builds up the antibodies in children under one year of age by the use of Salk vaccine, and then feeds them Sabin vaccine after they have become one year of age.

The contention that public health authorities cannot play a meaningful role in administering prescription drugs used in immunization programs and will have serious repercussions because of the likelihood of communicable disease epidemic is therefore without basis. In the first place, we are only concerned with vaccines which carry with them a medically cognizable risk as was found by the jury in the case at bar; and in the second place, there is nothing which would prevent the health departments from following the procedures used by Dr. Casso and other McAllen pediatricians. The Sabin vaccine is not the only vaccine. The Salk vaccine was the first breakthrough in the control of poliomyelitis and there has never been any question raised regarding the efficacy of the Salk vaccine which is a killed virus vaccine. There was certainly no evidence introduced in the trial of the case that the procedure of first injecting with Salk vaccine when the child was under one year of age and following with Sabin vaccine after the antibodies had been built up confused or frightened the patients of Dr. Casso and the other pediatricians. If this procedure was successfully carried out in the private practice of medicine there is no reason why a similar procedure could not be used as a guideline for immunization programs on a State level.

The Petitioner places a great deal of reliance on the case

of Gravis vs. Parke-Davis & Co., 502, SW 2d 863 (Tex. Civ. App. Corpus Christi 1973), which was fully considered and discussed by the Circuit Court. This case is not in point. While it is a products liability case, it involves a fact situation whereby Mrs. C. K. Gravis underwent an initial examination in an emergency room in the hospital at Alice, Texas, and subsequent examinations and tests necessitated an exploratory operation. On October 24, 1963, she was administered a spinal anesthetic containing three different drugs. An intestinal obstruction was found and corrected. Later, after she had been moved back to her room Mrs. Gravis felt abnormal and couldn't move her legs.

Mrs. Gravis brought suit against Parke-Davis & Co., Winthrop Laboratories, Inc. and Sterling Drug Co. for personal injuries sustained by Mrs. Gravis. The case was tried before a jury; however, at the conclusion of the plaintiff's case the drug company moved for an instructed verdict or in the alternative to withdraw the case from the jury and render judgment as a matter of law. The motion was granted by the trial court on the basis that there was no evidence that the drugs were impure or defective. All of the evidence indicated to the contrary. Neither did the plaintiff rule out all of the other possible causes of the injuries which could establish substantially, at least, that the defective drug was the only cause * * * evidence on the critical issue of the existence of a defect in the drugs was not established.

While at this point the case was disposed of the Court went ahead to discuss by way of dicta that "We believe that it was unreasonable to suppose that a drug manufacturer must go beyond the physician and give actual warnings to the patient. Once the physician has been warned, the choice of which drugs to use, and the duty to explain the risks involved, is his. These drugs were manufactured for administration only by a physician or other authorized person. Generally speaking, only a physician would understand the propensities and dan-

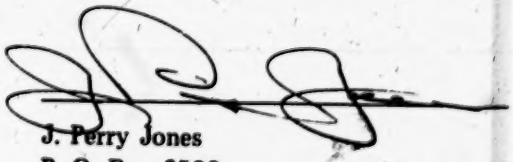
gers involved. The doctor is a learned intermediary between the manufacturer and the ultimate consumer."

There is no question but that there is a distinct difference between the responsibility of a drug manufacturer to warn of any risks associated with the sale of over-the-counter drugs and the warning which the ultimate consumer is entitled to when he has a face-to-face meeting with his physician. In such cases where there is a face-to-face meeting between the physician and the patient the manufacturer need not specifically warn each and every patient. While in the aforementioned Gravis-Parke-Davis & Co. case there was failure of proof that the drugs were impure or defective, all of the drugs and procedures used were administered personally by the physician who has long been held to be the learned intermediary between the manufacturer and the ultimate consumer. As stated in the Petition for Writ of Certiorari, a different panel of the Fifth Circuit has held that a physician in such position is not required to inform his patients of all risks involved in the treatment offered. He must act only as would a reasonable medical practitioner in the same circumstances. Karp vs. Cooley, 493 F. 2d 408 (5th Cir. 1974).

CONCLUSION

For the reasons stated, the Petition for Writ of Certiorari should be denied and the opinion of the United States Court of Appeals for the Fifth Circuit should be affirmed.

Respectfully submitted,



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CERTIFICATE OF SERVICE

I certify that on this the____ day of November, 1974, I mailed, certified mail, return receipt requested, two copies of Respondent's brief to Attorneys Clifford, Warnke, Glass, McIlwain, Finney & Spradlin, 815 Conneciticut Avenue, N. W., Washington, D. C. 20006, and to Attorneys Eberle, Berlin, Kading, Turnbow, Gillespie & McKlveen, 300 North Sixth Street, Post Office Box 1368, Boise, Idaho 83701.

J. Perry Jones

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In the Supreme Court of the United States

OCTOBER TERM, 1974

No. 74-501

WYETH LABORATORIES, a Division of American Home Products Corporation, a Delaware corporation,

Petitioner,

vs.

EPIFANIO REYES, Individually and as next friend of Anita Reyes, a minor,

Respondent.

MOTION FOR LEAVE TO FILE BRIEF AMICUS CURIAE

The American Academy of Pediatrics respectfully moves the Court for leave to file the attached brief *amicus curiae* in support of the petition for a writ of certiorari filed by petitioner Wyeth Laboratories, a division of American Home Products Corporation. The consent of the attorney for the petitioner has been obtained. The consent of the attorney for the respondent was requested but refused.

The American Academy of Pediatrics is a not-for-profit scientific and educational organization. The over-all objective of the Academy is to maximize the quality and quan-

tity of medical care available to children. Membership in the Academy is limited to certified pediatricians possessing at least five years specialized practice in pediatrics.

The Academy, through its Committee on Infectious Diseases, has supported the development of safe, effective immunization programs for many years. In performing this work the Academy frequently has acted at the instance of, or in cooperation with, the United States Government. Of vital interest to the Academy has been the prevention and control of poliomyelitis through public participation in immunization programs.

The Academy seeks leave to file a brief *amicus curiae* which discusses the effects of the decision of the court below upon immunization programs operated by public health authorities to prevent the spread of infectious disease among children. The Academy firmly believes that the decision of the court below requiring a manufacturer to warn vaccine recipients in a state public health program of remote, isolated risks thwarts a strong public policy favoring universal participation in immunization programs to eliminate infectious disease among children.

Respectfully submitted,

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November 27, 1974

In the Supreme Court of the United States

OCTOBER TERM, 1974

NO. 74-501

WYETH LABORATORIES, a Division of American Home Products Corporation, a Delaware corporation,

Petitioner,

vs.

EPIFANIO REYES, Individually and as next friend of Anita Reyes, a minor,

Respondent.

BRIEF AMICUS CURIAE OF THE AMERICAN ACADEMY OF PEDIATRICS IN SUPPORT OF PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

Amicus curiae, the American Academy of Pediatrics, supports the petition of Wyeth Laboratories that a writ of certiorari issue to review the opinion and judgment of the United States Court of Appeals for the Fifth Circuit rendered in these proceedings on July 31, 1974.

Question Presented

Whether a judicially created rule requiring a manufacturer to warn vaccine recipients in a state public health program of remote, isolated risks contravenes a strong public policy favoring universal participation in immunization programs to eliminate infectious disease among children.

Statement of the Case

The Academy adopts the Statement of the Case set forth at pp. 6-7 of the Petition for Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit of Wyeth Laboratories, filed October 29, 1974.

REASONS FOR GRANTING THE WRIT

A JUDICIALLY-CREATED RULE REQUIRING A MANUFACTURER TO WARN VACCINE RECIPIENTS IN A STATE PUBLIC HEALTH PROGRAM OF REMOTE, ISOLATED RISKS THWARTS A STRONG PUBLIC POLICY FAVORING UNIVERSAL PARTICIPATION IN IMMUNIZATION PROGRAMS TO ELIMINATE INFECTIOUS DISEASE AMONG CHILDREN.

The United States in recent years has enjoyed extraordinary reductions in morbidity and mortality from many infectious diseases. Remarkable decreases in death rates from whooping cough, diphtheria and tetanus have been recorded. Smallpox has been absent for nearly a quarter of a century. Measles has become sufficiently uncommon that most young physicians have not seen a case, and its disastrous complication, encephalitis, is extremely rare. Recent programs directed at preventing German measles in women early in pregnancy have reduced infant death and disability significantly. Poliomyelitis has all but disappeared from this country.

This remarkable freedom from these serious infectious diseases was achieved through the nationwide concerted efforts of many groups. The United States Public Health Service, state and local health departments, the private sector of medicine, scientific investigators, pharmaceutical manufacturers and medical organizations such as the American Academy of Pediatrics and the American Public Health Association—each played a significant role in the fight against infectious disease. Reflecting the public interest in winning this fight, state law-making bodies have also entered the battle.

The Texas legislature has required by statute that all children be immunized against poliomyelitis, rubella, diphtheria, rubeola, tetanus, and smallpox before entering elementary school. 67 Texas Rev. Stat. §2.09(a) (1971). The Texas legislature has also required that the State Department of Public Health should provide the required immunizations to children where there is no local provision for such services. 67 Texas Rev. Stat. §2.09(d) (1971). These provisions of Texas law evidence a strong public policy favoring universal participation in immunization programs to combat infectious disease.

A ruling by the Federal courts requiring a manufacturer to warn vaccine recipients in a state public health program of remote, isolated risks would contravene this policy. For Texas school children who are required to take the vaccine the warning would be superfluous since they have no choice in the matter under state law. For other citizens of Texas and for citizens of other states which permit individual choice in the matter, the warning would discourage many persons from taking the vaccine with the potentially adverse consequences—both to the individual and to the community—discussed below.

A simple statement that ingestion of the Sabin vaccine might infrequently transmit polio to the vaccine recipient would actually mislead the potential recipient by focusing on the remote risk of taking the vaccine while ignoring the far greater risk, associated with not taking the vaccine, of remaining susceptible to the polio virus. If a person's consent to taking the vaccine is to be truly "informed", a warning must convey to him the relative risks of contracting polio with and without the vaccine. The difficulty lies in framing such a warning that will adequately convey to the potential recipient the relative risks, which will be comprehensible to all persons who must take the vaccine,

and which will not unduly frighten potential recipients so as to weaken immunization programs.

Even for the expert the relative risks of contracting polio associated with taking and not taking the vaccine are difficult to quantify because they are derived from projections, epidemiologic interpretation, and statistical understanding. To describe adequately the relative risks would require a complex statement that many people would not understand or which might frighten away potential recipients. Experiments have shown that as information imparted with respect to a drug becomes more detailed and complex, the potential recipient's comprehension of the information declines and fewer people are willing to take the drug. L. Epstein and L. Lasagna, "Obtaining Informed Consent", 123 Archives of Internal Medicine 682 (June 1969).

The danger of confusing and frightening away potential recipients of the Sabin vaccine is heightened where the warning is to be communicated directly by the drug manufacturer to the ultimate recipient. Ordinarily, the courts have required that a prescription drug manufacturer communicate warnings only to the health professional prescribing the drug. E.g., *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82, 85 (8th Cir. 1966). This rule has the practical advantage of laying the responsibility of communicating the warning to the patient on the health professional with whom the patient has immediate contact. The health professional enjoys the advantage of being able to tailor warnings given to the patient so as to fit the patient's capacity for understanding and so as to minimize undue fears in the patient. Furthermore, he probably enjoys the patient's respect for his judgment, possibly as the result of a long-term relationship or simply because the patient has sought him out. The manufacturer, most likely physically as well as psychologically distant, does not enjoy comparable ad-

vantages. In order to convey a warning the manufacturer must necessarily resort to impersonal techniques such as a printed consent to be signed by the recipient of the vaccine. The language of such a consent cannot be adjusted to meet the individual patient's capacity for comprehension or to allay his undue fears.

The requirement of a warning directly from the manufacturer to the recipient would inevitably confuse and frighten at least a portion of the public and would decrease by a significant number the percentage of people immunized. Such a decline would portend new outbreaks of infectious disease such as polio. With the exception of smallpox the infectious agents responsible for these illnesses are ever present in this country. Relaxation of immunization efforts can only result in a renewed outbreak of one or more of these diseases. Indeed, some complacency resulting from the striking reduction in disease rates was associated with diminished rates of satisfactory immunization against these diseases in the past few years, as evidenced in isolated outbreaks of diphtheria, measles and poliomyelitis in 1970. Increased emphasis on immunization programs subsequently resulted in lower infection rates in 1971.

Recognizing that even the slightest relaxation in the battle against infectious disease could be disastrous, the State of Texas has embarked on a course aiming at universal immunization. It has required that all school children be immunized against certain infectious diseases, including polio, and it has directed the State Department of Public Health to make these vaccines available to the public. The courts should be wary of upsetting this laudable legislative goal by requiring a warning from the manufacturer of the drug to the recipient which would have the effect of confusing and frightening the potential recipient.

Without in any way commenting on the particular facts of the case at bar, the American Academy of Pediatrics recognizes the very remote risk of a person contracting polio as a consequence of receiving a polio vaccine. However infinitesimal the number of such cases, the Academy strongly supports efforts to eliminate these cases entirely. In addition, the Academy urges legislative consideration of public programs to provide for the care of the few people who contract polio from the vaccine. But the Academy strongly believes that informed medical experience has demonstrated conclusively that the only efficacious way of eliminating risks of diseases such as poliomyelitis has been pursuant to immunization programs, which can only be effective if backed by state legislation and which ought not to be weakened by a judicially-created rule.

If this Court denies the petition for a writ of certiorari and the award to plaintiff in this case is sustained, the manufacturer will be required to warn directly each potential recipient of the vaccine. The inevitable result will be that fewer people will seek immunization. It would be a most tragic irony if the courts, in striving to help one victim, were by that very act to add to the ranks of victims of infectious disease.

CONCLUSION

For the reasons stated, a writ of certiorari should be granted to review the judgment and opinion of the United States Court of Appeals for the Fifth Circuit.

Respectfully submitted,

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NOV 29 1974

SUPREME COURT, U. S

IN THE

Supreme Court of the United States

OCTOBER TERM, 1974

No. 74-501

WYETH LABORATORIES, a division of American Home Products Corporation, a Delaware Corporation,
Petitioner,

v.

EPIFANO REYES, individually and as next friend of Anita Reyes, a minor,
Respondent.

MOTION FOR LEAVE TO FILE BRIEF AMICUS CURIAE AND BRIEF AMICUS CURIAE IN SUPPORT OF A PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT.

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PRESS OF BYRON S. ADAMS PRINTING, INC., WASHINGTON, D. C.

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MOTION FOR LEAVE TO FILE BRIEF AMICUS CURIAE ON BEHALF OF THE CONFERENCE OF STATE AND TERRITORIAL EPIDEMIOLOGISTS i

BRIEF AMICUS CURIAE IN SUPPORT OF A PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT 1

ARGUMENT FOR GRANTING WRIT

A. It is the Judgment of the Public Health Authorities of the States of the United States, the State Epidemiologists in Charge of Immunization Programs in the United States, that the Effect of the Decision of the Court Below Would Be To Endanger Very Seriously Disease Prevention in the United States 1

B. In Particular, the Effect of the Reyes Decision Would Be Felt in State and National Efforts to Control Poliomyelitis, a Very Serious Crippling and Killing Disease in the United States, at a Time When Immunization Levels are Already Becoming Dangerously Low in the High-Risk Populations of Children of Ages Up to Four Years 2

C. The Effect of this Decision Would Be To Require a "Warning" to Parents of Young Children Who Are at High Risk for Poliomyelitis in the Community Against the Extremely Small, Almost Unmeasurable Risk at the Present Time (From 1 in 2 Million to 1 in 15 Million Doses) from the Vaccine Itself. The Requirement of Such a Warning To Be Given by the Commercial Drug Company Marketing the Product Would Violate the Accepted Practices of State and National Epidemiologists 4

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Because They Think Polio Is "Conquered." The Rates of Immunization in Children are Constantly Going Down. These Children Aren't "Sick" and the Parents Have Little Incentive To Take Them for Immunizations, Particularly If They Have No Regular Family Pediatrician or Doctor. The "Warning" Would Not Only Further Discourage Such Parents, but, in Epidemic Situations, Would Lead the Community To Assume that the Infected Children Around Them Might Have Gotten the Disease from the Vaccine and So Would Further Reduce Immunization, Even with Assurances from Officials that the Epidemic was from Natural Causes 4-5

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1974

No. 74-501

WYETH LABORATORIES, a division of American Home Products Corporation, a Delaware Corporation,
Petitioner,

v.

EPIFANO REYES, individually and as next Friend of Anita Reyes, a minor,
Respondent.

MOTION FOR LEAVE TO FILE BRIEF AMICUS CURIAE ON BEHALF OF THE CONFERENCE OF STATE AND TERRITORIAL EPIDEMIOLOGISTS.

The Conference of State and Territorial Epidemiologists, pursuant to Rule 42 of the Rules of this Court, hereby respectfully moves the Court for leave to file a brief *amicus curiae* in this case. Consent for the filing

of such a brief has been obtained from the petitioner Wyeth Laboratories, but has not been granted by attorneys for the respondent Epifanio Reyes.

Movant, the Conference of State and Territorial Epidemiologists, is a membership organization composed of the heads of the communicable disease programs of each of the fifty states, Puerto Rico, and the Virgin Islands. The Conference represents physicians and scientists who specialize in the field of epidemiology and who are engaged, along with other state officials and local health officers, in conducting public health programs for the control of diseases among the people. The Conference is an affiliate of the Association of State and Territorial Health Officers and is an official advisory group to the United States Public Health Service.

It is the intention of the epidemiologists of the country to call the attention of the Court to the dangerous effect which the decision below, if upheld, could have upon the nation's preventive medicine programs. A major keystone of these efforts is the extensive, community-wide use of immunological agents. In a quite literal sense, these products of scientific research have saved millions of lives and prevented untold misery among the people of the world.

We are sure that the members of this Court do not need to be reminded at length of the historical significance of immunization against disease. In past centuries, millions more people were killed by infectious and communicable diseases than by all the wars of man. Total populations were decimated in Europe

and Asia. These scourages have only recently come under control.

By its nature the Conference has a unique interest in the outcome of this litigation. Public health and epidemiology (the study of the distribution and determinants of diseases in man and the application of epidemiological methods to prevent disease) are fields of professional specialization. Programs of disease prevention are directed by governmental agencies of the Federal and State levels where epidemiologists play key investigative, analytical, and evaluative roles.

The decision to conduct a public health program to prevent a particular disease and to utilize a particular immunization agent is made by a trained epidemiologist on behalf of the public and after a very detailed, comprehensive review and balancing of risk and benefits. Any determination of the obligation of a manufacturer to disclose risks directly to participants in a public immunization program unavoidably affects the exercise of professional judgment by trained epidemiologists. The impact of the lower court's holding on the discharge of the epidemiologist's professional responsibility cannot be adequately raised and discussed by either the petitioner or the respondent.

In the opinion of the Conference, the decision below, if left standing by this Court, will seriously endanger disease prevention in the United States and have a highly deleterious effect on state and national efforts to control such epidemic diseases as poliomyelitis. The brief submitted by the Conference with this motion sets forth the particular issues which we believe merit the Court's consideration. We respectfully submit that

this case is one of importance to the nation's public health, and that review by the Court is merited.

Respectfully submitted,

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November 29, 1974

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Respondent.

BRIEF AMICUS CURIAE IN SUPPORT OF A PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT.

ARGUMENT FOR GRANTING WRIT

A. It is the Judgment of the Public Health Authorities of the States of the United States, the State Epidemiologists in Charge of Immunization Programs in the United States, that the Effect of the Decision of the Court Below Would Be To Endanger Very Seriously Disease Prevention in the United States.

This brief as *amicus curiae* is presented to the Supreme Court of the United States in support of the petition for a writ of certiorari in *Reyes* v. *Wyeth Laboratories,* 498 F.2d 1264 (5th Cir. 1974).

The Conference of State and Territorial Epidemiologists is a membership organization composed of the state-employed heads of the communicable disease programs of the state governments of the 50 states, Puerto Rico, and the Virgin Islands. The Conference represents physicians and scientists who specialize in the field of epidemiology, the study and control of epidemic diseases. The Conference is an affiliate of Association of State and Territorial Health Officers and is an official advisory group to the United States Public Health Service, working closely with the Center for Disease Control in Atlanta, Georgia.

It is the judgment of these state public health authorities that the effect of the decision of the United States Court of Appeals for the Fifth Circuit would be a very serious blow to state and national programs of disease control in the United States.

B. In Particular, the Effect of the Reyes Decision Would Be Felt in State and National Efforts to Control Poliomyelitis, a Very Serious Crippling and Killing Disease in the United States, at a Time When Immunization Levels are Already Becoming Dangerously Low in the High-Risk Populations of Children of Ages Up to Four Years.

The vaccine involved in the *Reyes* case was Sabin oral poliomyelitis vaccine, a biological product of very, very high safety and internationally proved effectiveness in immunizing humans against the disease of poliomyelitis. Because of the tragic results of this disease, especially among young children, the campaign to produce an immunizing agent was one of the priority areas of scientific research in this country and in other countries for many decades.

The development of the Sabin vaccine was one of the great triumphs of medical scientific research in this

century. The mass immunization programs of the late 1950s and the 1960s reduced very substantially the cases of poliomyelitis in the United States.

Now that these national mass immunization programs have been so very effective in reducing poliomyelitis in the adult population and among most children, the target group for national and state efforts is the children being born into the population without protection against the disease. The national government, through the U.S. Public Health Service and its Center for Disease Control, conducts two kinds of campaigns on a constant basis to obtain immunization of these high-risk children: (1) encouragement of public health clinics and privately practicing pediatricians and family physicians to immunize infants under their care as soon as possible in their lives; and (2) national support of vigorous campaigns of *mass immunization* of these high-risk children in any area of the country where poliomyelitis breaks out in epidemic proportions.

The child who contracted polio in this case, Anita Reyes, was at high risk for polio naturally in the community; in fact, she lived in the area of highest risk in the United States at that time, Hidalgo County in Texas, close to the Mexican border. The second-mentioned type of national campaign against a local epidemic was in force at the time in southern Texas under the guidance and surveillance of the state epidemiological authorities and the U.S. Public Health Service. The efforts of the State and the U.S. Public Health Service and the scope of the epidemic are described in the official publication of the Center for Disease Control, *the Morbidity and Mortality Weekly Report,* for May 30, 1970. The Federal policy of mass immuni-

zation with Sabin vaccine for the control of local outbreaks of the disease is described graphically in a series of such campaigns in the above publication over a period of years leading up to and including the particular epidemic in which the Reyes child contracted the disease. These reports are cited in Note 1 at pages 16 and 17 of the petition of Wyeth Laboratories for the writ of certiorari. This series of reports, more than anything else we could cite, proves the national significance of these immunization programs and proves their *success in controlling the spread of the disease* through this use of Sabin vaccine on a mass basis in clinics and doctor's offices.

The result of enforcement of the decision below could seriously jeopardize *both* the general campaign to immunize young children, and the vigorous national campaigns to control epidemics among such small children, as in southern Texas.

C. The Effect of this Decision Would Be To Require a "Warning" to Parents of Young Children Who Are at High Risk for Poliomyelitis in the Community Against the Extremely Small, Almost Unmeasurable Risk at the Present Time (From 1 in 2 Million to 1 in 15 Million Doses) from the Vaccine Itself. The Requirement of Such a Warning To Be Given by the Commercial Drug Company Marketing the Product Would Violate the Accepted Practices of State and National Epidemiologists.

D. In the Reyes Case Situation, Such a Warning by the Drug Company Could Create Alarm in the Public in the Face of a Natural Epidemic. The People Are Already Resisting Taking the Vaccine Because They Think Polio Is "Conquered." The Rates of Immunization in Children are Constantly Going Down. These Children Aren't "Sick" and the Parents Have Little Incentive To Take Them for Immunizations, Particularly If They Have No Regular Family Pediatrician or Doctor. The "Warning" Would Not Only Further Discourage Such Parents, but, in Epidemic Situ-

ations, Would Lead the Community To Assume that the Infected Children Around Them Might Have Gotten the Disease from the Vaccine and So Would Further Reduce Immunization, Even with Assurances from Officials that the Epidemic Was from Natural Causes.

It should be realized that Sabin poliomyelitis vaccine is an extremely safe product, much safer than the vast majority of all types of products for human consumption. In large part, this is due to the high level of safety required by the Federal Government for the marketing of all biological products. Also, we are able to provide statistics on the safety of Sabin vaccine to a much greater degree of certainty than on most products because of the unprecedented international testing of the vaccine in all parts of the world and the close surveillance of the outbreak of communicable disease in this country by the national and state governments. The opinion of the Court in the Fifth Circuit in *Reyes* does not contradict this conclusion. The Court specifically found that the vaccine was not unreasonably dangerous. This is a vast understatement. The Court nevertheless found the product "defective," its conclusion of liability under a products liability theory, on the sole basis that a direct warning to the purchaser or user (the child and her parents) was not given by the manufacturer.

The Sabin vaccine is a prescription drug. A detailed package insert accompanied the drug and provided to physicians, public health authorities, and clinic personnel a detailed description of the vaccine, its use, and its contraindications. Plaintiff in this case in no way challenged the content of the warning in the package insert. The description therein had the specific approval of the Federal Division of Biologics Standards. It should be noted that the package insert

itself proves the very high degree of safety of the vaccine in use here. The package insert pointed out that the vaccine had no known side effects. In general use, there were no recommended precautions or contraindications to its use. Few products of any kind, even after marketing, are free of defects in this high degree. The only specific precautions made in the insert do not relate to the safety of the product, but to its effectiveness in being retained by the patient, or its effectiveness in a patient who may already have polio. The insert suggests that the vaccine not be given to individuals suffering from "acute illness, other than minor, afribrile upper respiratory infection" and "in the presence of persistent vomiting or diarrhea."

As to the inherent risk in the vaccine of producing polio, the statistics concerning the risk as set forth in the package insert in children under 5 years of age are as follows: from Type III, 0.53 per million doses; from Type I 0.17 per million; and for Type II, none. The alleged contracting of polio in the plaintiff was from Type II. In the *Reyes* case, therefore, the "warning" would have been of a statistical risk of about 1 in 5.88 million! It should be clear that this is *not* a risk of proved vaccine-produced disease. It is merely statistically possible cases within the period of biological compatability.

Under these conditions, it was not the practice of epidemiologists or physicians to give a "warning" to parents or to children of this statistically remote possibility of contracting polio from the vaccine. Such a low risk would be very remote in relation to benefit in any medical, therapeutic situation. In preventive medicine, where the child or other recipient is not "sick," it is even more difficult for the patient to weigh

risk and benefit. At present, the immunization rate in children is going down steadily because so many parents think that the disease of poliomyelitis is "conquered" and there is no sense in taking the trouble or expense of immunization. In early October of 1974, the Center for Disease Control released figures indicating that immunization levels for children of 1-4 had dropped in 1973 to 60.4 percent. (*New York Times*, Oct. 10, 1974, at p. 10.) On a nationwide basis, this means that 40% of these children are not immunized; a level at which the disease could certainly burst out in epidemic proportions among this huge population of children at risk.

In the face of this problem the *Reyes* decision would require this alarming warning to be given by the manufacturer to the parents. The alarming nature of the warning does not relate so much to the statistics of the risk, which many people would not fully understand anyway. It would relate to the risk of "polio," a dreaded disease in children, which could be fatal or result in severe crippling. Yet, the *benefit* of the vaccine would be to prevent this very same dread disease and risk of death and crippling. In the *Reyes* situation, the risk of natural polio in the community was vastly greater than from the vaccine. The evidence at the trial was not contradicted that there was an epidemic at that time that in Hidalgo County and Dr. Neal Nathanson, Professor of Epidemiology at Johns Hopkins University School of Public Health, placed the risk to the Reyes child at 1 in 3000 children in her age group. (Record, p. 1381)

Under these conditions, the practice was clear. A warning of this kind was not given by the epidemiologists or in the public health clinic where Anita Reyes received the vaccine. To do so would, in the view of

the professionals involved, have unduly alarmed parents and discouraged them from bringing the children for immunization. If the drug company were to be required to provide a warning in some broadcast nature, or by signs in the clinic, or by written notices, the parents could further be suspicious of the public health authorities for encouraging immunizations, and could suspect that the outbreak of cases of polio was caused by the vaccine rather than by the natural epidemic. This fear would be very difficult to combat. The fact that the early cases had occurred before a mass program of immunization had begun would be obscured or not noticed. Statistically compatible cases would be publicly attributed to the vaccine and all efforts to combat the disease would be compromised.

E. The Fifth Circuit Opinion Requires a Direct Warning by the Manufacturer to the Public in Contravention of Texas Law and the Federal Food, Drug, and Cosmetic Act of 1938 Regarding Prescription Drugs.

The opinion of the Court of Appeals is contrary to Texas law and Federal law in requiring a direct warning to the public on risk concerning a prescription drug. The Court did not challenge the fact that the vaccine was licensed by Wyeth as a prescription drug. It would have been a violation of law for the manufacturer to advertise to the public or to provide a warning to patients in the public health clinic where Anita Reyes received her vaccine. The same conditions existed at the clinic as in a private doctor's office in that this was regular medical care. It was not a mass distribution of the vaccine in a school or gymnasium as occurred in the late 1950s and 1960s, or as in the *Davis* case cited below. *Davis* v. *Wyeth Laboratories*, 399 F.2d 121 (9th Cir. 1968).

We firmly disagree with the opinion below that the method of delivering medical care in this public health clinic was *not* such that the vaccine was administered as a prescription drug. The clinic was operated and supervised by physicians. A trained clinical, public health nurse, in accordance with accepted medical practice, gave the vaccine as she would a "shot" with a hypodermic needle, or as she would offer other clinical services.

There is nothing in the law of Texas or the Federal food and drug laws which supports removing the restrictions on prescriptive drugs because they are administered in a public health clinic. In fact, the leading case on the prescriptive drug manufacturer's duty in Texas, *Gravis* v. *Parke-Davis and Co.*, 502 S.W.2d 863 (Tex. Civ. App.—Corpus Christi., 1973) includes not only physicians, but "other authorized persons" in the group who administer the drugs under prescription. This group of "authorized persons" would certainly include clinical nurses administering drugs of this type in a clinic. The *Gravis* case specifically holds "These professionals are in the best position to evaluate the warnings put out by the drug industry." 502 W.W. 2d at 870. The public health nurses, as well as the physicians, in the *Reyes* situation received the full warning from the manufacturer, Wyeth Laboratories. That warning was evaluated and the physicians and nurses made the professional judgment not to pass on this extremely small risk information to the parents. There is nothing in the Texas law to support any other position. The Court of Appeals attempts to avoid this Texas law by an unsupported assertion that the drug was not distributed as a prescription drug. This distinction has no support in Texas law and conflicts with the *Gravis* case

in including "other authorized personnel" in administering prescription drugs.

The decision of the Fifth Circuit in *Reyes* also is in conflict with the decision of another panel of the same Circuit in interpreting Texas law on warnings to patients by physicians. *Karp* v. *Cooley.*, 493 F.2d 408 (5th Cir. 1974). In that case, the Court upheld the settled Texas law that the scope of the warning in an informed consent of the patient is governed by medical practice and the judgment of reasonable medical practitioners in the same or similar circumstances. Expert testimony was required to provide proof of the accepted medical standard. Had this rule of Texas law been applied in *Reyes*, the plaintiff would have failed to meet this requirement of proof. It was unrebutted that the accepted practice of public health programs, physicians, and nurses was not to warn of the remote risks to the Reyes child in receiving the vaccine in the light of the vastly greater benefits to be derived in receiving it during an epidemic outburst of polio in Texas. It was error under Texas law to allow a jury to contradict this judgment of medical professionals and to require a warning by the manufacturer. See also *Wilson* v. *Scott*, 412 S.W.2d 299 (Tex. 1967).

F. The Circuit Court Committed Error in Not Reversing the Trial Court's Denial of the Defendant's Motion for a Directed Verdict and Judgment in View of the Overwhelming Medical and Scientific Proof that the Reyes Child's Disease Was Not Caused by the Vaccine.

The Conference of State and Territorial Epidemiologists must also support the petition for a writ of certiorari on the grounds that the Court of Appeals committed reversible error in not reversing the trial court's denial of a directed verdict and judgment,

n.o.v., on the basis that the medical and scientific evidence was overwhelmingly in favor of the defense that the Reyes child did not contract her disease from the vaccine but as a result of the natural epidemic in the community.

The Conference is a group of scientists. It is interested in the administration of justice as bearing some direct relationship to scientific truth and findings. When decisions fly in the face of overwhelming scientific proof to the contrary, particularly in the field of immunology and epidemiology wherein the Conference of State and Territorial Epidemiologists has its own expertise and experience, this can be described only as very disturbing.

The defense in this case produced an unrebutted picture of a united medical and scientific community that there was no proved causal relationship between the Reyes child's disease and the vaccine. The head of the Federal Government's agency regulating this field, himself a respected scientist, testified for the defense as did the head of the Federal Government's laboratory in the field. Outstanding experts in virology, epidemiology, and pediatrics from the nation's leading universities testified. In rebuttal, the plaintiff produced as an "expert" only the local general practitioner who treated the Reyes child *after* she had contracted the disease.

In the face of this overwhelming evidence, the Court of Appeals asserted that this was "conflicting credible evidence" and "within the jury's prerogative." The Court, in an incredible understatement, said that "The evidence for Wyeth was *somewhat* persuasive; there is no doubt about it." (Emphasis supplied.) The Court then asserted that the evidence for Reyes "was

substantial and at least as persuasive, looking at the record coldly." 498 F.2d at 1289.

It seems to this *amicus* that no review of this record can support this last statement. To arrive at it, the Court and jury would have to reject all of the expert testimony *plus* the overwhelmingly high statistical probability that the Reyes child's disease was natural. The risk *at most* in the vaccine was 1 in 5.88 million. In natural disease in the community it was 1 in 3000. Only the patient's own doctor, a general practitioner, gave his opinion that the vaccine *caused* the disease.

The Texas law requires that questions of medical and scientific causation be determined on the basis of expert testimony. Such determinations must be based on reasonable probability. The burden of proof here was on the plaintiff, not on the defendant. All of the weight of the expert evidence and scientific probability was overwhelmingly on the side of the defense. Under the instructions given by the trial judge, the jury was allowed to dismiss all of the National Government officials and all of the scientific experts as long as they "believe" Dr. Casso. The jury was obviously troubled by the charge, since they came back and asked what "preponderance" of the evidence meant. The *only* explanation the trial judge gave them was that preponderance did not depend on number of witnesses. The only meaning the jury could give to this was that, if they found Dr. Casso credible, they could ignore the array of experts. They could ignore both numbers and quality of testimony in a *scientific* judgment. The trial judge gave as an example that they could believe one expert who said a horse was white as against ten who said it was black.

This interpretation of a jury's prerogatives is in direct contradiction of two other leading decisions of

this same Fifth Circuit Court of Appeals. In *United States* v. *Hoxsey Cancer Clinic*, 198 F.2d 273 (5th Cir. 1952) the Court rejected as entitled to no weight the opinions of general practioner osteopaths on the cause of cancer and reversed a jury determination. In *United States* v. *Weir*, 281 F.2d 850 (5th Cir. 1960) the Court rejected the testimony of five general pracitioners as *not substantial evidence* in the field of arthritis in opposition to an array of experts in the field. We submit that these cases represent an enlightened and proper application of the law to cases requiring expert, scientific evidence. In *Reyes*, we have an example of an erroneous application of a discredited practice of not upsetting jury verdicts if there is any evidence to support them. In a simple case of credibility, this rule may make sense on an appellate level. It does not make sense or justice in a complex, scientific case where expert, scientific evaluation is essential to any proper conclusion and where the statistical probabilities are overwhelmingly against the party bearing the burden of proof. Neither the evidence nor the statistical probabilities supported the plaintiff herein. We therefore support the petition for a writ of certiorari.

Respectfully submitted,

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November 29, 1974

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MOTION FOR LEAVE TO FILE BRIEF AMICUS CURIAE IN SUPPORT OF PETITIONER'S PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

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MOTION FOR LEAVE TO FILE BRIEF AMICUS CURIAE

The American Medical Association respectfully moves for leave to file a brief *amicus curiae* in support of the petition for a writ of certiorari in this case. Petitioner's attorneys have consented to the filing of this brief.

Respectfully submitted,

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BRIEF AMICUS CURIAE IN SUPPORT OF PETITIONER'S PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

Interest of the Amicus Curiae

The American Medical Association is the national professional association of physicians. Founded in 1846, the Association has a current membership of 207,000 physicians and serves as the representative of the medical profession in the United States and its Territories.

The objects of the American Medical Association, as written into the Association's Constitution more than a century ago, are "to promote the science and art of medicine and the betterment of public health." The Purposes and Responsibilities of the American Medical Association

were further defined by the House of Delegates, the Policy-making body of the Association, in 1967, as follows:

"It is the responsibility of the American Medical Association, as the representative of the American medical profession, to continue to foster the advancement of medical science and the health of the American people.

"Its continuing purposes are to meet this responsibility through the following means:

"1. By encouraging the further development of medical knowledge, skills, techniques and drugs; and by maintaining the highest standards of practice and health care.

"2. By creating incentives to attract increasing numbers of capable people into medicine and the other health-care professions.

"3. By advancing and expanding the education of physicians and other groups in the health-care field.

"4. By motivating skilled physicians who have the art of teaching to apply themselves to developing new generations of excellent practitioners.

"5. By fostering programs that will encourage medical and health personnel to serve voluntarily in the areas of need for medical care.

"6. By developing techniques and practices that will moderate the costs of good medical and health care.

"7. By seeking out and fostering means of making all health-care facilities—physicians' offices, hospitals, laboratories, clinics and others—as efficient and economical as good medical practice and attention to human values will permit.

"8. By combining the utilization of the latest knowledge for prevention and treatment with the vital healing force of the physician's personal knowledge of and devotion to his patient.

"9. By maintaining the impetus of dedicated men and women in providing excellent health care by preserving the incentives and effectiveness of unshackled medical practice.

"10. By maintaining the highest level of ethics and professional standards among all members of the medical profession.

"11. By continuing to provide leadership and guidance to the medical profession of the world in meeting the health needs of changing populations."

The 1967 definition of the responsibilities of the American Medical Association in respect to the continuing advancement of the science and art of medicine and service to the public inculcates the principles upon which the Association agreed at its first meeting. The 1846 assembly acted on two issues requiring immediate attention: the establishment of a committee to promulgate ethical standards for the profession and a committee to concentrate on the elevation of standards of medical education that would assure the provision of quality medical services to the public.

At the annual meetings in 1847 and each year thereafter until federal and state health departments were active in epidemiology the House of Delegates received reports from its Committee on Practical Medicine on the "improvements effected in this country in the management of individual diseases" and "the progress of epidemics." In 1850, for example, the report included information on the sources of typhus fever and means suited to their ex-

tinction. By 1853, the House of Delegates was recommending that local societies appoint committees "to record the prevalence of epidemics or other diseases and the general state of health in their respective communities and to transmit said reports to the committees of the Society on Epidemics, through the state societies where they exist."

This concern that proper protection be afforded to the people of this country against the preventable diseases has continued throughout the history of the American Medical Association. As effective vaccines against communicable diseases have been developed and tested, the House of Delegates has consistently urged all physicians to support campaigns to motivate the public to protect the children of the country by proper immunization against the preventable diseases. The recent declining levels of immunization in pre-school children has been of particular concern to the Center for Disease Control and physicians. The AMA House of Delegates endorsed "Immunization Action Month" in 1973 and 1974 as one way to promote an increased immunization level for children against the preventable diseases.

Campaigns to promote the use of poliomyelitis vaccine by the public were endorsed by the House of Delegates in 1954, 1955 and 1957. In 1957, a national conference of state medical societies was held and poliomyelitis vaccine campaigns were organized by state and local medical societies. By 1964, 87.6 percent of children 1-4 years of age were immunized against polio. By 1972, the percentage had dropped to 62.9 and in 1973 to 61.2.

The importance of continuing efforts to assure a preventable disease-free population cannot be overemphasized. Public policy at the national and state levels supports mandatory immunization programs for pre-school children to

prevent polio, rubella, mumps, pertussis, tetanus and diphtheria. Immunization Action Month-1973 and 1974 represents a cooperative effort sponsored and coordinated by the Center for Disease Control, national medical and health organizations, a number of pharmaceutical companies and a number of voluntary action groups. The campaign urges physicians to review the immunization status of their patients, especially pre-school children, and to act to increase the immunization level of children against the preventable diseases.

Many pre-school children would not have the benefit of available vaccines if state and county public health departments are to find the conduct of such programs hampered by a lack of physician personnel to make individual medical judgments as to the advisability of administering one or more vaccines to pre-school children. This potential effect of the decision of the Fifth Circuit Court of Appeals in the *Reyes* case leads the American Medical Association to respectfully urge the Supreme Court to issue a writ of certiorari in this case of national significance and first impression.

Position Statement

It is the position of the American Medical Association that the nation's public health goal of complete protection of every child from paralytic poliomyelitis must be supported and encouraged to assure the nation-wide eradication of this infectious disease. This goal cannot be achieved unless primary immunization of infants and routine recall immunization are encouraged and made available through physicians' offices, clinics, public health departments and institutions. Only in this manner can the entire population be protected since such programs prevent exposure to infection from the chief spreaders of wild polioviruses, infants and pre-school children.

The extension of the tort doctrine of strict liability to the vaccines when used in public health programs does not serve the public interest and, in fact, may impede achievement of the public health goals of the country. The decision that the risks to the community of the spread of an infectious disease outweigh the statistically low danger of risk to individuals in the suspectible population group to whom the vaccine will be administered is made by the state. Texas made this decision for all pre-school age children. More specifically in this case, the decision was made on the basis of a possible community emergency stemming from the reported incidence of paralytic poliomyelitis in the area.

To argue that knowledge of a public health department's manner of administering routine and community-wide immunization programs imposes on a vaccine manufacturer a duty to either provide individual warnings to the ultimate consumer or to be responsible for seeing that the public health department provides such individual warnings overlooks the public policy considerations. Public policy in Texas, as in most states, mandates specified routine immunizations for all pre-school children. Public policy in Texas also encourages routine immunization for infants regardless of ability to pay, since the state health department provides vaccines to the local departments for administration to those unable to pay. The thrust of this public policy is the protection of the entire population as opposed to the preferences of an individual.

In public health immunization programs, a medical judgment is made on behalf of the community. The medical judgment would not be at variance from an individualized medical judgment, however, for any infant who had not received the vaccine prior to the determination that an epidemic threatened or existed in the community. The balancing of the risks against the benefits has been made by pedi-

atricians, public health physicians and physicians generally and it is based on a consensus of the opinion in the medical and scientific communities. Oral poliovirus vaccine is considered the vaccine of choice for community-wide vaccination programs and for routine and recall immunization in infancy and childhood because of its ease of administration, immunogenic effectiveness, protective capacity, potential for the eradication of poliomyelitis and statistically minimal risks. By 1966, the risk to adults of naturally occurring poliomyelitis had been reduced to such an extremely low level that continued immunization of adults was not recommended provided continued immunization of infants and pre-school children, the chief spreaders of wild polioviruses, was continued to protect susceptible adults indirectly by preventing virus circulation and therefore exposure to infection.

This case raises issues of national significance that have not been decided by the United States Supreme Court. The extension of the tort doctrine of strict liability to vaccines used in public health programs of national importance is an issue upon which the Supreme Court should rule for the guidance of the District and Circuit Courts of Appeal in the federal system. In the absence of such a ruling, disruption of immunization programs may have the undesirable effect of leaving large numbers of the citizens of the United States with inadequate protection against the spread of communicable diseases which can be prevented by vaccines and deprive a large class of indigent citizens of the only preventive health care available to them.

The extension of the tort doctrine of strict liability in this type of case is inappropriate. By making the manufacturer liable for sale of a vaccine considered unavoidably unsafe because of the miniscule risk associated with its

use and finding the product in "an unreasonably dangerous condition" when sold without specific warnings or individualized medical judgment that it is necessary and desirable for a particular patient flies in the face of the public health policy of this country. The court, in effect, is requiring the manufacturer either to give to the ultimate consumer the essential information for a valid, informed consent or arrange for a physician to be present and provide the elements necessary for a valid, informed consent. Public policy establishes that informed consent is not a requirement for vaccine administration. Consent has been supplied by statute and the federal and state public health department policies. Clarification of the applicability of public policy in public health immunization programs is necessary if the entire population is to receive the maximum protection possible from the spread of preventable communicable diseases.

Conclusion

Public policy considerations have been balanced consistently against possible injury to individuals by the courts in reaching decisions. Public policy favors public health immunization programs as necessary to serve the public interest by assuring preventable disease-free populations. The determination of public policy in health matters is based upon the consensus of scientific and medical experts in infectious diseases and preventive measures. Such determinations are not made without careful consideration of the risks to individuals and the resultant benefits to the population. The success of the public health immunization programs in this country can be shown by the eradication of smallpox, and the reduced incidence of

paralytic poliomyelitis, diphtheria, typhoid and other communicable diseases. This trend can be reversed in a short time if immunization programs are not encouraged and supported. The resultant loss of productive lives in this country would create an intolerable and unnecessary burden on society.

For the above reasons, the American Medical Association respectfully urges the Supreme Court to issue the writ of certiorari to review the judgment and opinion of the United States Court of Appeals for the Fifth Circuit.

Respectfully submitted,

/s/ Betty Jane Anderson
Betty Jane Anderson
Attorney for the American Medical Association
Amicus Curiae

November 25, 1974

SUPREME COURT, U. S.

Supreme Court, U. S.

DEC 16 1974

MICHAEL RODAK, JR., CLERK

IN THE

Supreme Court of the United States

OCTOBER TERM, 1974

No. 74-501

WYETH LABORATORIES, a Division of American Home Products Corporation, a Delaware corporation,
Petitioner,

v.

EPIFANIO REYES, individually and as next friend of Anita Reyes, a minor,
Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

PETITIONER'S REPLY TO RESPONDENT'S BRIEF IN OPPOSITION TO PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

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PETITIONER'S REPLY TO RESPONDENT'S BRIEF IN OPPOSITION TO PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

Respondent's Brief in Opposition to Petition for a Writ of Certiorari contains numerous erroneous or misleading statements of fact, and fails to respond adequately to the legal arguments advanced by Petitioner.

I.

On page 2 of his Brief, Respondent asserts that neither of the questions presented in the Petition for a Writ of Certiorari was raised in the lower courts. This is simply not true. Petitioner argued in the trial court and in the Court of Appeals that Sabin oral polio vaccine is a prescription drug, licensed by the Federal Government for sale only as a prescription drug under the appropriate Federal statutes. *See* 42 U.S.C. § 262(a); 21 U.S.C. § 353(b); 42 C.F.R. §§ 72.200-.240 and 73.1020-.1028 (all of which were cited and relied upon in Petitioner's appellate brief). Petitioner therefore had no duty under local tort law to warn the ultimate consumer of its vaccine. Wyeth has consistently maintained that Federal law controlled regarding the discharge of its duty as a manufacturer of prescription drugs and that, in the absence of a holding that it provided an inadequate warning to the appropriate health authorities responsible for dispensing the drug, it could not be held liable.

Respondent has failed to refute Petitioner's argument that the Federal Food, Drug, and Cosmetic Act of 1938, 52 Stat. 1040 (1938), as amended, 21 U.S.C. § 301, *et seq.* (1970), and the Public Health Service Act, 58 Stat. 702 (1944), as amended, 42 U.S.C. § 262, *et seq.* (1970), have preempted the field of law applicable to the labeling of prescription biological drug products and that it was therefore error for the lower courts to dispose of this case solely on the basis of local tort law.

Petitioner has established that the labeling of prescription drug products shipped in interstate commerce is subject entirely to Federal law and regulation and

that the States are without power to impose contrary restraints in this area. It is undisputed that Sabin oral polio vaccine is a prescription drug and that Wyeth fully complied with the provisions of Federal law regarding the labeling of this product. Respondent's contention that the package insert which accompanied the vaccine was inadequate is unfounded, and was not adopted by any of the lower courts. Moreover, this contention turns entirely on the very Federal law which Respondent argues is not controlling here.

Once the manufacturer of a prescription drug has complied fully with the provisions of Federal law regarding the labeling of its product and has furnished this warning to the health professionals responsible for administering the drug, the manufacturer has completed his obligation to the public. To require the manufacturer of a prescription drug to provide written material to the ultimate consumer other than the labeling required by Federal law subjects the manufacturer to obligations inconsistent with the requirements of Federal law and interjects State tort law into an area which Congress has clearly pre-empted.

II.

The second question raised in the Petition for Certiorari, that the Court of Appeals erred in its application of Texas law, was thoroughly briefed in the lower courts. A substantial portion of Petitioner's appellate brief was devoted to the proposition that Wyeth had no duty under Texas law to warn the ultimate consumer of the dangers inherent in its drug. Moreover, *Gravis* v. *Parke-Davis & Co.*, 502 S.W.2d 863 (Tex. Civ.App.—Corpus Christi, 1973), relied upon by Wyeth

in its Petition for Certiorari, was not decided until after its appellate brief had been submitted to the Court of Appeals. That the Court of Appeals considered *Gravis* is obvious. It was cited as Texas authority for the elements which must be established to recover under § 402(a) of the Restatement (Second) of Torts. 498 F.2d at 1272; Appendix A to the Petition for Certiorari at p. 8(a). Respondent's assertion that the second question raised in the Petition for Certiorari was not presented to the courts below is groundless.

Although the Court of Appeals cited and applied a portion of the *Gravis* holding, the court failed to discuss or even mention the following statement from *Gravis*, 502 S.W.2d at 870:

> "We hold that it is unreasonable to demand that the manufacturer of drugs specifically warn each and every patient that receives drugs prescribed by the physician *or other authorized persons.* The entire system of drug distribution in America is set up so as to place the responsibility for distribution and use upon professional people. The laws and regulations prevent prescription-type drugs from being purchased by individuals without the advice, guidance and consent of licensed physicians and pharmacists. These professionals are in the best position to evaluate the warnings put out by the drug industry." (Emphasis added.)

The Court of Appeals' holding in *Reyes* v. *Wyeth* cannot be reconciled with this Texas court decision, and Respondent makes no attempt to do so in its Brief. In view of the practical consequences of the Court of Appeals' decision, fully discussed in the Petition for Certiorari filed herein, this conflict with Texas law is a sufficient basis on which to grant the Petition.

III.

There are several inaccurate and misleading references in Respondent's Brief which require clarification. The last paragraph of page 3 of Respondent's Brief refers to the Report of Surgeon General's Committee on Oral Poliomyelitis Vaccines, which was published in July 1964. Respondent's use of that report distorts the findings of the Committee. Respondent does not mention the Committee's conclusion that it was not possible to prove that any individual case was caused by the vaccine and that no laboratory tests available could provide a definite answer. The Committee's conclusion was simply that "considering the epidemiological evidence developed with respect to the total group of 'compatible' cases, the Committee believes that at least some of these cases were caused by the vaccine."

The same report outlined the "risk factor" associated with the oral vaccine and concluded as follows:

> "For Type III, only 1 case in 2.5 million doses administered; for Type I, only 1 in 6 million; and for Type II, only 1 in 50 million."

On page 7 of Respondent's Brief, reference is made to the testimony of Dr. John P. Fox, Associate Dean, School of Public Health, and Professor of Epidemiology, University of Washington. Respondent fails to point out that when asked to express an opinion regarding the origin of Respondent's illness, Dr. Fox attributed the illness to a virus of "wild origin" and further testified that:

> "It was not Type I vaccine virus, it was virus which had infected her probably prior to the administration of the vaccine, and which was circulat-

> ing rather abundantly in the neighborhood as is evidenced from the occurrences of other cases at about this time." Court of Appeals Appendix, p. 1166

Respondent's intimation that Sabin oral polio vaccine is more dangerous than other vaccines (Respondent's Brief, p. 11) is conclusively refuted by the testimony of Dr. Fox. Speaking of the relative safety of the Sabin vaccine, Dr. Fox stated that:

> "Amongst those that have been licensed and used, almost the safest that I can think of are the live polio vaccines. The frequency of disease attributable to the use of these vaccines is of such a low order of magnitude that offhand I cannot think of anything comparable to it. . . ." Court of Appeals Appendix, pp. 1169-1170

Respondent's reference to the testimony of Dr. Neal Nathanson, Professor of Epidemiology at Johns Hopkins University, and Editor of the American Journal of Epidemiology, is misleading and largely meaningless. Dr. Nathanson's reference to a risk of vaccine induced polio of one in 5000 was based on an assumption of the very fact at issue, i.e., that Respondent's disease was vaccine induced. When asked to assess the odds of vaccine induced disease in Respondent's case, Dr. Nathanson stated: "I would calculate that I would be 99.9 percent certain that this case was a naturally acquired case of polio." He added that he "felt that there was no clear reason to consider any of these cases (those in Hidalgo County) as vaccine related." Court of Appeals Appendix at 1383, 1381.

CONCLUSION

Respondent's Brief in Opposition to the Petition for a Writ of Certiorari fails to diminish the weight of the reasons advanced for granting the Writ. Of particular importance is the disruptive effect which the decision below will have on the public health system of this country. The importance of this issue is illustrated by the concern of such groups as the American Medical Association, the American Academy of Pediatrics, and The Conference of State and Territorial Epidemiologists, all of whom have moved for leave to file briefs *amici curiae* in support of the Petition. In view of the gravity of this issue, we urge this Court to grant a Writ of Certiorari to review the opinion of the United States Court of Appeals for the Fifth Circuit.

Respectfully submitted,

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